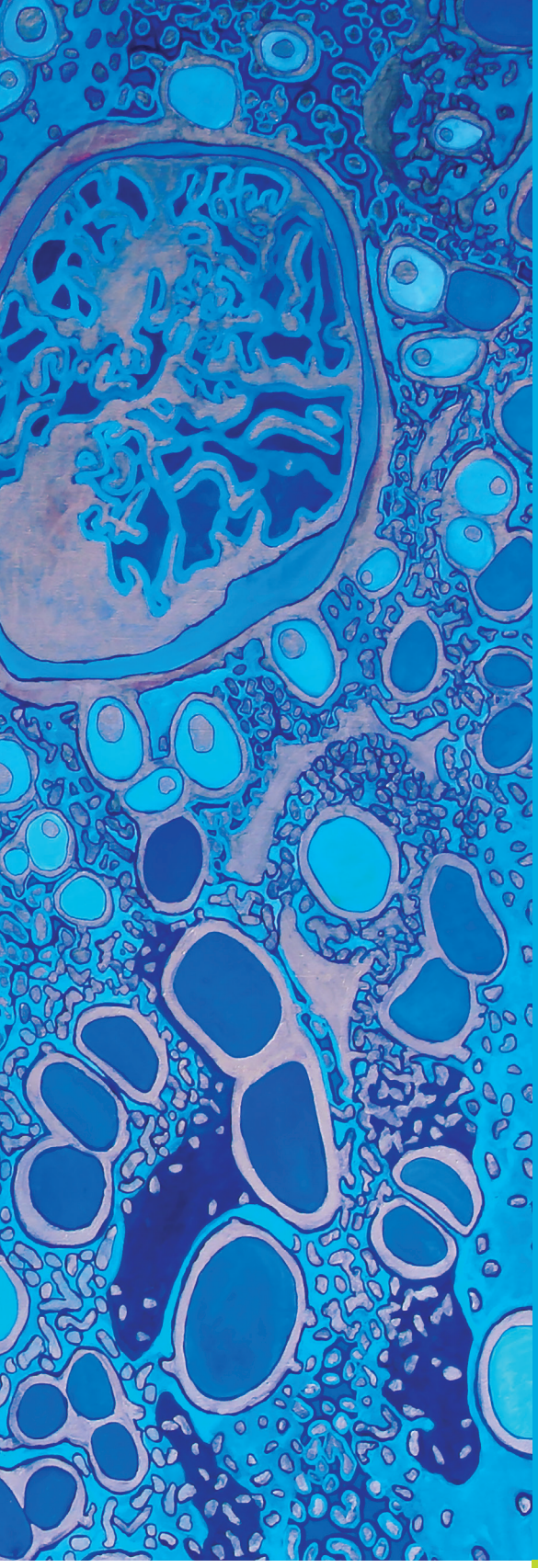


A New Vision for Discovery

FNIH
Foundation for the
National Institutes of Health

2014 Summary Annual Report

WHO WE ARE

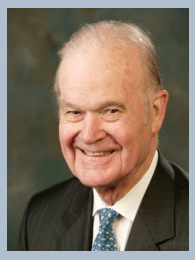
The Foundation for the National Institutes of Health (FNIH) is an agile team of biomedical scientists, program managers and fundraisers. We work with a large network of forward-thinking leaders and organizations to seek new knowledge and apply it to improve health, lengthen life and reduce illness and disability. We orchestrate productive research collaborations, incubate new research models and channel resources for maximum impact. In all we do, we support the mission of the National Institutes of Health, the largest biomedical research agency in the world, as it works to *turn discovery into health.*

The FNIH is a not-for-profit 501(c)(3) charitable organization established by Congress in 1996.

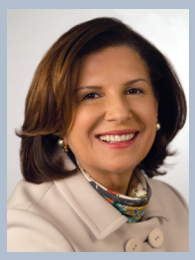
ABOUT THE COVER

Type 2 diabetes, the most common form of diabetes, affects more than 100 million Americans who already have it or are at high risk. The FNIH is a key partner in an initiative to find biological pathways that are the best candidates for new treatments—for diabetes and other serious conditions. The cover illustration by artist Jody Rasch is an abstract interpretation of clusters of cells, including those that produce insulin.

Letter from the Chairman and President



CHARLES A. SANDERS, M.D.
CHAIRMAN



MARIA C. FREIRE, PH.D.
PRESIDENT

There is an old adage that it takes years to become an overnight sensation. Indeed, in many fields, decades of planning, study and hard work eventually make possible what seems a sudden success story. For example, the phrase "public-private partnerships" is ubiquitous in some circles, but for many, a new concept. For the Foundation for the National Institutes of Health (FNIH), however, it is a successful way to drive progress—a formula we have used for nearly 20 years to build innovative and strategic alliances between the public and private sectors. These partnerships are crucial to the advancement of biomedical science because they provide a vehicle to create and support trailblazing projects and programs that enhance the mission of the National Institutes of Health (NIH).

Another of today's most popular terms—born from decades of scientific and clinical research—is "precision medicine": tailoring treatment to the needs and make-up of an individual. The potential impact on health due to such technologically advanced medicine is enormous and demonstrates why funding for medical research must be, and must remain, a national priority. This new way of preventing, diagnosing and treating disease did not happen overnight; it took strong investment from the U.S. government for basic research, unwavering dedication from scientists in academia, the private and the public sectors, generous philanthropic support from donors and, importantly, the unselfish commitment of thousands of patients who volunteer to become partners in the medical research enterprise.

The FNIH is uniquely positioned to work with these stakeholders to create partnerships that have transformed business-as-usual into business success. In this report, we are pleased to highlight some of the pioneering programs of the robust FNIH portfolio, including a new model for clinical trials that speed patient access to investigational drugs (Lung-MAP), new interventions that enhance the lives and health of some of the world's poorest people (HIT-TB) and a radically new approach to early-stage drug development (AMP).

Yet there are challenges. In recent years, the NIH budget has suffered losses, both in real and inflation-adjusted dollars. A government shutdown and sequestration compounded the situation. If as a society we are to continue progress towards revolutionizing our ability to tackle disease and disability, this trend must be reversed to regain momentum.

The staff of the FNIH is inspired by our mission to help the NIH turn discovery into improved health. With the generous support of the biomedical community, our funders and our partners, we continue to leverage public and private funds to advance biomedical science forward through innovative leading-edge initiatives.

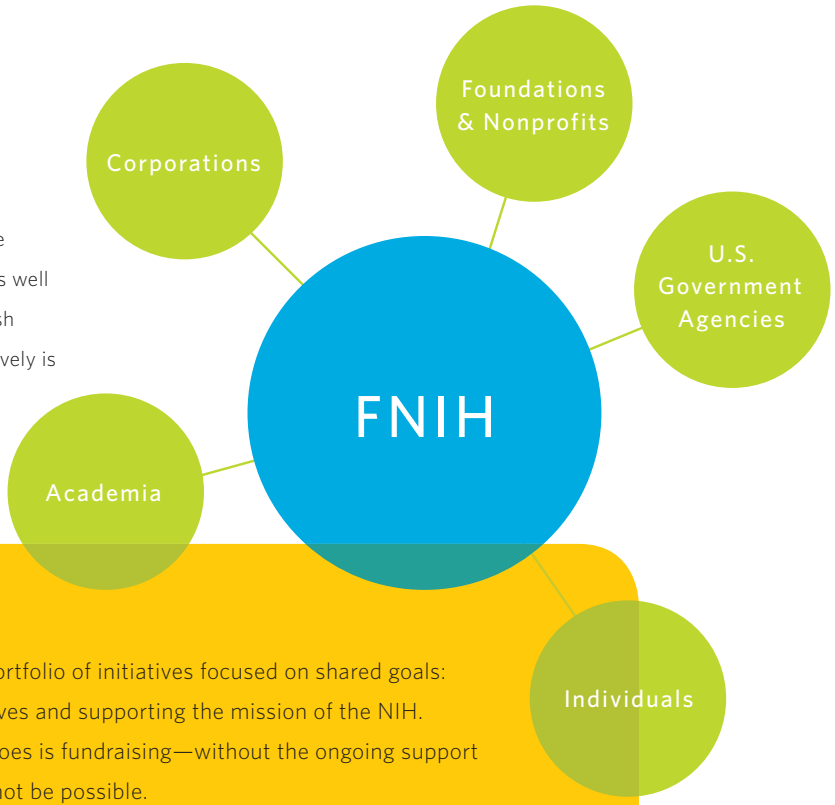
CHARLES A. SANDERS, M.D.
CHAIRMAN

MARIA C. FREIRE, PH.D.
PRESIDENT

FNIH At-a-Glance

OUR PARTNERSHIPS

Everything we do depends on collaboration. The partnerships we forge provide funding support as well as expertise and resources to help us accomplish and expand our work. What we achieve collectively is far greater than that of any single organization.



WHAT WE DO

The FNIH stands at the center of a broad portfolio of initiatives focused on shared goals: advancing biomedical science to improve lives and supporting the mission of the NIH. One of the most important jobs the FNIH does is fundraising—without the ongoing support of our contributors these initiatives would not be possible.

RESEARCH PARTNERSHIPS — We develop collaborations with top experts from government, industry, academia and the not-for-profit sector and provide a neutral environment where we can work productively toward a common goal. Examples include:

- **Portfolio Supporting NIH Research** — Supporting and raising funds for multiple projects initiated by the NIH, while also convening the right partners within and outside of the NIH.
- **Global Health** — Coordinating and operating more than 50 collaborative projects in over 33 countries, including the Grand Challenges in Global Health (GCGH) supported by the Bill & Melinda Gates Foundation.
- **Biomarkers Consortium** — Initiating and managing more than 16 projects funded with over $50 million in private dollars, designed to discover and develop biological markers to support new drug development, preventive medicine and medical diagnostics.

SYMPOSIA, EVENTS & EXHIBITS — We organize and facilitate more than 60 events each year, creating a forum for innovative thinkers in biomedical sciences to share ideas and engage the public in disease and health awareness.

FELLOWSHIPS & AWARDS — We provide funding for training for early-career scientists, along with support and recognition for researchers whose findings have advanced biomedical science.

SUPPORT FOR THE NIH RESEARCH ENTERPRISE — Each year, FNIH undertakes a variety of projects to support the NIH community of researchers, patients and stakeholders. For example, in 2014, the FNIH raised funds to support renovations and enhancements to the The Edmond J. Safra Family Lodge, a facility that provides temporary housing for families of patients receiving care at the NIH Clinical Center.

A new vision for discovery. Today's health challenges are too complex to be solved by any single organization—government, business, academia or not-for-profit—working in isolation. But often these organizations are not experienced at identifying partners and forging productive relationships. At the FNIH, we are connected to key players in all of these sectors, and we can facilitate their collaboration because we have created management and funding models that make large-scale, multi-partner projects succeed. This is our vision for discovery—and it works.

Cultivating Collaborations that Thrive

Joining forces to accelerate drug development

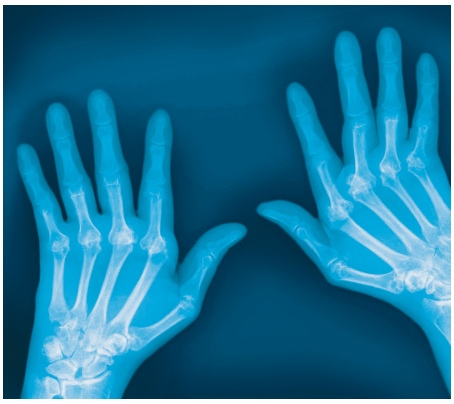
New medicines that show promise in the laboratory often do not succeed in human testing. In fact, about 95 percent fail, typically late in the clinical trials process after millions of dollars have been invested. Such a high-cost, low-reward pipeline points to the need for a better understanding of how diseases develop at the molecular level—which is why the FNIH is helping to lead an unprecedented partnership to fill this need. Launched in 2014, the Accelerating Medicines Partnership (AMP) is a $230 million, five-year effort joining the forces of the FNIH, the NIH and the Food and Drug Administration (FDA) with those of not-for-profit organizations and 10 biopharmaceutical companies to devise a radically new approach to early-stage drug development. These companies have agreed to share expertise, resources and data to answer a critical question: Which biological pathways underlying a given disease are the best candidates for targeting new treatments? Instead of having different organizations pursue disparate pathways in isolation, AMP will generate pre-competitive, disease-specific data on the genetic and biological markers most likely to yield success when used as targets for new medicines. The data will be publicly available to the biomedical community so that many can use it as the foundation for drug discovery. *(For a list of AMP partners, see page 17.)*

AMP: TYPE 2 DIABETES

More than 100 million Americans already have type 2 diabetes or are at high risk, and 382 million people worldwide have a type 2 diagnosis. Although therapies are available, none can reverse the disease process or prevent the progression that leads to life-altering complications such as cardiovascular and kidney disease, limb loss and blindness. AMP partners will leverage the substantial amount of data already available from patients with type 2 diabetes and those at high risk to identify and validate DNA regions critical in the development or progression of the disease, with an eye toward identifying potential drug targets.

AMP: ALZHEIMER'S DISEASE

Alzheimer's disease (AD) is the most common form of dementia, a condition that affects 36 million people globally—a number expected to skyrocket to 115 million by 2050 unless an effective therapy is developed. Scientists know that people with AD have the signature protein-based brain lesions called plaques and tangles; however, efforts to harness this knowledge to develop new therapies have not succeeded. AMP partners are working to establish an expanded set of biological markers that are present when AD develops, and then determine which are most promising for developing new treatments and predicting the likelihood of clinical response. The project will involve the large-scale analysis of brain tissue from AD patients and clinical trials to validate newly identified biomarkers.



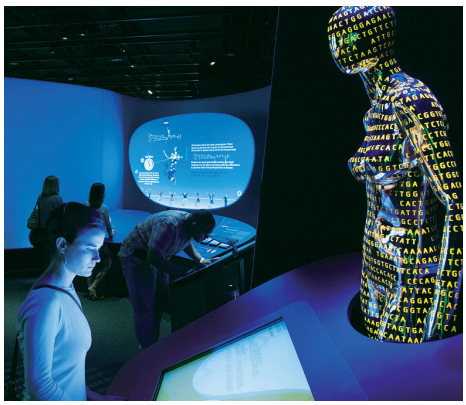
AMP: RHEUMATOID ARTHRITIS & LUPUS

Rheumatoid arthritis (RA) and lupus are just two of many disorders that occur when the immune system mistakenly attacks parts of the body that it is designed to protect, leading to inflammation that destroys tissues. Anti-inflammatory treatments can help, but most people with RA respond to current treatments only partially or temporarily. In the case of lupus, no effective targeted therapies exist for the most severe forms of the disease. AMP partners will analyze tissue and blood samples from people with RA and lupus to pinpoint genes, proteins, chemical pathways and networks involved at the cellular level. This is essential for developing targeted treatments for these debilitating conditions, but it also could shed light on the autoimmune process implicated in a wide range of diseases.

Creating Impact Beyond the Laboratory

The search for better tuberculosis treatments

Tuberculosis (TB) affected nine million people and caused 1.5 million deaths worldwide in 2013, affecting children and adults with HIV in developing nations particularly hard. TB is a bacterial infection that spreads through the air and attacks the respiratory system and other organs. Successful treatment requires taking multiple medications for several months, leading many patients to drop out prematurely—and remain contagious. Compounding this problem is the growing number of cases that are resistant to available drugs, most developed in the 1970s. With funding through the Bill & Melinda Gates Foundation, the Identification of high-quality HITs for Tuberculosis (HIT-TB) project at the FINH is helping to accelerate the search for new TB medications that could shorten and simplify treatment. This partnership includes the National Institute of Allergy and Infectious Diseases (NIAID), multiple pharmaceutical and agrichemical companies and several academic institutions to speed identification of compounds best suited for testing as potential drugs. The partners have shared their compound libraries and are using high-throughput screening to evaluate many molecules at once to identify "hits" to be prioritized for further study.



Genome exhibit reaches millions

Between June 2013 and August 2014, roughly three million Smithsonian visitors experienced *Genome: Unlocking Life's Code* at the National Museum of Natural History, an exhibition made possible through funds raised, in part, by the FNIH. The result of a collaboration between the museum and the National Human Genome Research Institute, *Genome* awed visitors with the complexity and power of the human genome using 3-D models, interactive displays, custom animations and videos of real-life stories. It celebrated the 10th anniversary of the Human Genome Project and the successful sequencing of the human genetic blueprint, helping viewers understand how this knowledge is revolutionizing our understanding of human development, diversity and society, especially health and disease. In addition to the 4,400-square-foot exhibition itself, which took two years for museum designers and educators to develop and build, *Genome* included public events, educational symposia, an educators' guide and the website *www.unlockinglifescode.org*. *Genome* is now on a multi-city tour that will take it to museums in California, the Midwest and Ontario through early 2018.

For an exhibition schedule, visit http://unlockinglifescode.org/traveling-exhibit.

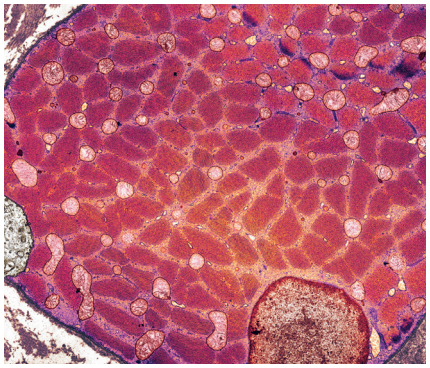
Support for a game-changing scientist

What if we could remove and replace damaged or defective parts of human DNA? Scientists have been working to find such a genome-editing tool, but Jennifer Doudna, Ph.D., Professor of Biochemistry, Biophysics and Structural Biology and a Howard Hughes Medical Institute Investigator at the University of California, Berkeley, stands apart. Dr. Doudna has focused her research on the structure of RNA, the molecule that carries out DNA instructions for creating the proteins that drive processes in the body. The FNIH awarded her the Lurie Prize in Biomedical Sciences in 2014 for that body of study, which includes her work on CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), that are repetitive RNA sequences in bacteria that play a role in their immunity. Doudna discovered that pieces of CRISPR RNA team up with a protein called Cas9 to cut through the DNA of an invading virus. Doudna and her team then engineered their own RNA/protein combination and showed it can be used to precisely edit the DNA of plants, animals and humans. This CRISPR tool has to be managed with careful attention to bioethical concerns, but it could function as "molecular scissors" that can fix faulty genes underlying a range of diseases and health conditions.

Bringing Bold Thinking to New Models

Lung cancer: pioneering a more efficient approach to clinical trials

Patients with advanced squamous cell lung cancer have few good treatment options beyond surgery, yet the pace of traditional clinical trials remains slow, with most potential treatments never making it to the bedside. The Lung Cancer Master Protocol (Lung-MAP) trial, the result of a partnership that includes the FNIH, is pioneering a new model designed to speed access to investigational drugs for patients and allow multiple researchers to share one umbrella structure and recruitment process, significantly increasing their efficiency. Launched in June 2014, Lung-MAP uses genomic profiling technology to test patients for over 200 cancer-related genetic alterations, then assigns them to one of a number of investigational treatment studies based on their genetic profile. Within its first six months, Lung-MAP was enrolling patients at more than 400 sites in 39 states. The trial will add new investigational treatments over time, with the ultimate goal of testing 10 to 12 targeted therapies in 5,000 patients over the next five years. Besides the FNIH, partners in the effort include the National Cancer Institute, SWOG Cancer Research, Friends of Cancer Research, Foundation Medicine, five pharmaceutical companies and several lung cancer advocacy groups. *(For a list of Lung-MAP partners, see page 17.)*



Sarcopenia: defining diagnostic criteria for age-related muscle loss

Sarcopenia—age-related muscle loss and weakness—affects nearly 1 in 3 people over 60 and half of those over age 80. However, lack of an evidence-based definition for sarcopenia has limited our ability to understand its progression and develop strategies for prevention and treatment. This changed in April 2014 with the landmark publication of six special online articles in the *Journals of Gerontology: Medical Sciences*, which set forth data-driven diagnostic criteria for sarcopenia, including definitions of grip strength and muscle mass. The articles resulted from a collaborative project by the FNIH Biomarkers Consortium, the FDA, the National Institute on Aging and several pharmaceutical companies, in which researchers analyzed data from nine long-term epidemiologic studies involving over 26,000 healthy participants to generate a definition of sarcopenia. In addition to diagnostic criteria, the 2014 publications provide specific characterizations of how low lean mass and low strength relate to problems with mobility. This new information is expected to influence treatment decisions and help identify groups of at-risk patients who are good candidates for testing interventions. *(For a list of Biomarkers Consortium—Sarcopenia initiative partners, see page 17.)*

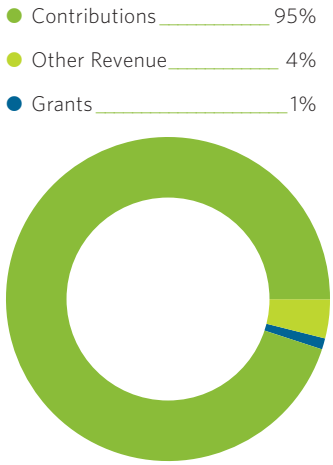
River blindness: moving beyond control to elimination

Over the past few decades, focused efforts to control the tropical disease onchocerciasis, or river blindness, have drastically lowered incidence in South and Central America, but the disease continues to have a devastating impact in sub-Saharan Africa. River blindness is caused by *Onchocerca volvulus* worms, which are transmitted to humans through repeated bites from infected blackflies. Mass administration of the drug ivermectin is an effective control strategy, but it does not guarantee elimination of the disease from a population, as people can carry the worms without exhibiting symptoms. The FNIH is working with the NIAID to determine if a blood or urine test could be developed to identify people who are carriers of adult female *Onchocerca volvulus* worms (OvAF). Once inside a human host, these females produce smaller larvae that over time can cause chronic skin disease, severe itching and eye lesions that lead to blindness. Knowing if someone is a carrier would ensure they could be treated and prevent transmission of the worms to uninfected blackflies. The FNIH and NIAID are studying OvAF and OvAF-infected humans to identify biomarkers in blood and urine that might indicate the presence of the female worm, and then test and validate the most promising candidates. The ultimate goal is a point-of-care test that would help eradicate river blindness around the globe.

Financial Highlights

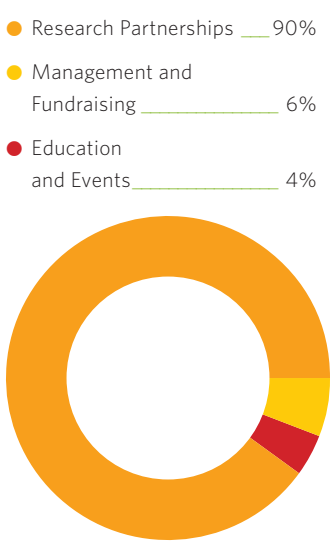
REVENUE AND SUPPORT	2014	2013
Contributions	$72,770,911	$57,747,975
Grants	634,635	887,026
Administrative fee	197,177	333,361
Government appropriations	500,000	500,000
Investment earnings	206,479	337,389
In-kind contributions	1,724,619	589,208
Donated services	188,637	43,000
Fundraising event	184,675	—
Other revenue	153,956	150,775
Reduction of future pledges	—	(214,788)
TOTAL REVENUE AND SUPPORT	**$76,561,089**	**$60,373,946**

2014 REVENUES



EXPENSES AND CHANGES IN NET ASSETS		
PROGRAM SERVICES		
Fellowships and training programs	$ 1,605,067	$1,381,328
Memorials, awards and events	442,058	1,299,278
Capital projects	103,421	38,754
Research partnerships	69,780,507	55,290,526
TOTAL PROGRAM SERVICES	**$71,931,053**	**$58,009,886**
SUPPORTING SERVICES		
Management and general	$3,928,920	$3,352,175
Fundraising	270,153	104,008
TOTAL SUPPORTING SERVICES	**$4,199,073**	**$3,456,183**
TOTAL EXPENSES	**$76,130,126**	**$61,466,069**

2014 EXPENSES



CHANGE IN NET ASSETS	$430,963	$(1,092,123)
NET ASSETS BEGINNING OF YEAR	91,138,418	92,230,541
NET ASSETS AT END OF YEAR	**$91,569,381**	**$91,138,418**

The Foundation's audited financial statements are available on request.

Our Donors

All FNIH donors play a critical role in providing the resources that are vital to our success. Unrestricted gifts allow us the flexibility to place them where they are most needed, from supporting core operations to developing new partnerships and emerging program ideas. Donors also can choose to restrict their gifts to one area of interest, such as a biomedical research program; a fellowship, lecture or symposium that trains scientists and helps them build their careers; or a specific laboratory or area of scientific research at the NIH.

We are grateful to the many individuals and organizations who made donations, gifts and pledges in 2014. Every attempt is made to list donors according to their wishes. For a more complete list of donors, funds and endowments, visit fnih.org/about/foundation/annual-reports. Please call 301.402.4976 if you have any questions.

OF EVERY DOLLAR SPENT, 94 CENTS ARE USED TO SUPPORT PROGRAMS AND JUST SIX CENTS FOR ADMINISTRATION AND FUNDRAISING.

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For 10 years, Charity Navigator has rated FNIH as an organization that exceeds industry standards and performs as well or better than most charities.

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[x] Superscript indicates number of years of consecutive giving.
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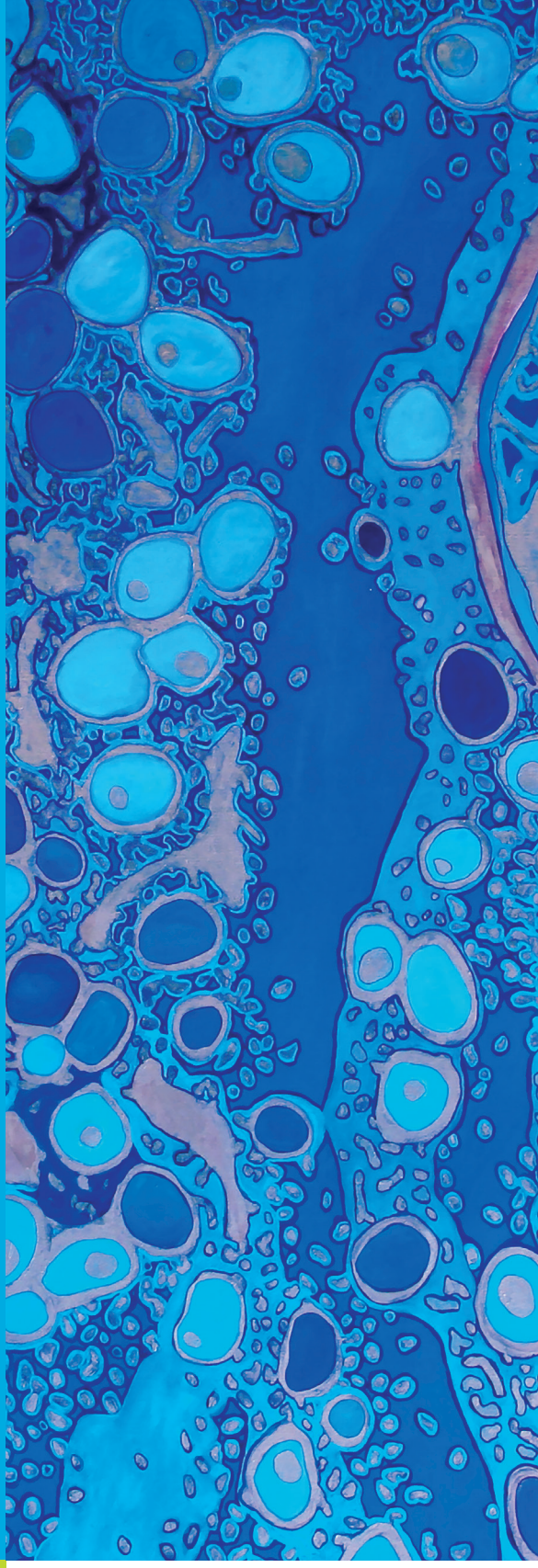

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