2020 Statutory Report

FNIH 25

Foundation for the
National Institutes of Health

Contents

In Memoriam

The FNIH remembers with respect, gratitude and deep affection Mrs. Buffy Cafritz and Dr. Michael Gottlieb, beloved individuals who helped forge our Foundation and made it thrive.

A renowned Washingtonian, Mrs. Cafritz is remembered for her commitment to her loved ones and her quintessential belief in bettering the lives of others through impactful philanthropy. During the 17 years as a Board member, along with decades in providing steadfast support to the FNIH, Mrs. Cafritz held biomedical research and education as critical to helping patients worldwide, a vision that embodied her forward thinking and intelligent leadership. Through her exemplary partnership with the FNIH, Mrs. Cafritz helped foster scientific innovation and advance pioneering research at the National Institutes of Health.

Dr. Gottlieb leaves a legacy of the millions of lives that will be touched by his work today and for generations to come. He served as Associate Director for Science at the FNIH, primarily leading projects on global health such as the Grand Challenges in Global Health initiative, after serving as a Branch Chief at the National Institute of Allergy and Infectious Diseases. We remember Michael as a beloved colleague and a passionate scientist. He was a well-respected leader around the globe, inspiring trust, loyalty and courage. Michael was generous, self-effacing, smarter than anyone in the room and he harbored a wicked sense of humor.

They will be truly missed and will not be forgotten.

FNIH 25
Foundation for the National Institutes of Health

Tab One
FNIH Overview

FNIH 25
Foundation for the
National Institutes of Health

The Foundation for the National Institutes of Health (FNIH) creates and leads alliances and public-private partnerships that advance breakthrough biomedical discoveries and improve the quality of people's lives in support of the mission of the National Institutes of Health (NIH), the premier medical research agency. The Foundation attracts and shares resources, organizes and administers research programs, enables insight and innovation, supports training and education, establishes standards, distributes expertise and disseminates knowledge supporting a wide range of health challenges.

The FNIH has raised over $1.2 billion, generating over $80 per $1 of NIH support. Through the American People's financial support of the Foundation's operations, the FNIH dramatically leverages their investment to nurture scientific expertise of incalculable value. In 2020, the FNIH earned the top designation of four-star honors from the nation's largest independent charity evaluator, Charity Navigator. Only 9 percent of charities evaluated received the highest rating for at least six consecutive years, indicating that the FNIH "outperforms most charities in America." The results of the evaluation include a perfect score for accountability and transparency as well as placement among the top medical research organizations in the country. Charity Navigator's rating acknowledges the FNIH for carrying out its mission in a way that is financially efficient, uses sector best practices and "exceeds industry standards." The FNIH's independent auditors issued a clean opinion on the 2020 Financial Statements (see Tab 7).

In April 2020, the NIH, with support from the FNIH, created the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership to develop and implement a research strategy to speed development of the most promising COVID-19 vaccines and treatments. ACTIV brings together NIH with its sibling agencies in the Department of Health and Human Services, including the Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority (BARDA) and Centers for Disease Control and Prevention (CDC); other government agencies, including the Department of Defense and Department of Veterans Affairs; the European Medicines Agency; and representatives from academia, philanthropic organizations and 20 biopharmaceutical companies. ACTIV has developed a collaborative, streamlined forum to identify preclinical treatments, accelerate clinical testing of the most promising vaccines and treatments, improve clinical trial capacity and effectiveness and accelerate the evaluation of vaccine candidates to enable rapid authorization or approval. Multiple ACTIV master protocols for COVID-19 treatments are underway.

The FNIH model is clear, flexible and – importantly – adaptable. The FNIH launched the GeneConvene Global Collaborative, designed to advance best practices and informed decision-making for the development of genetic biocontrol technologies to improve public health. It also launched a multi-site efficacy and safety trial of intrapartum azithromycin to research whether this therapy can reduce infection and sepsis in mothers and newborns. New Accelerating Medicines Partnership (AMP) programs in heart disease, common metabolic disease and gene therapy are under development.

The FNIH also celebrated the achievements of Dr. Aviv Regev, winner of the Lurie Prize in Biomedical Sciences and Dr. Michael Wilson, recipient of the Trailblazer Prize for Clinician-Scientists. Dr. Anthony S. Fauci was awarded the Charles A. Sanders, M.D., Partnership Award for his legacy of leadership and ongoing support of FNIH programs propelling research in lethal infectious diseases, most recently for COVID-19.

After a quarter-century of supporting the mission of the NIH, the FNIH continues to work with government and private sector partners to magnify impact and enhance preparedness and response to 21st century health and biomedical challenges.

Tab Two
Board of Directors

FNIH 25
Foundation for the
National Institutes of Health

Foundation for the National Institutes of Health

Board of Directors

as of December 31, 2020

Steven M. Paul, M.D. (Chairman)
Chief Executive Officer and Chairman, Karuna Therapeutics

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Distinguished Service Professor of Neuroscience, Pharmacology & Psychiatry,
Solomon H. Snyder Department of Neuroscience at Johns Hopkins University

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Former Chief Executive Officer, CoGenesys, Inc.

Mrs. William McCormick Blair, Jr. (Secretary)
Director Emeritus, Albert & Mary Lasker Foundation

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Buffy Cafritz
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Partner, Goldman Sachs & Company
Adjunct Professor, University of Virginia

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Director, Kovler Foundation; Director Emeritus, Sasha Bruce Youthwork, Inc.

Ronald L. Krall, M.D.
Adjunct Professor of Neurology, University of Rochester

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Former Chief Medical Officer and Executive Vice President, Pfizer Inc.

Julie Bell Lindsay
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Edison T. Liu, M.D., Ph.D.
President & Chief Executive Officer, The Jackson Laboratory

Joel S. Marcus
Executive Chairman and Founder, Alexandria Real Estate Equities, Inc.

Gilbert S. Omenn, M.D., Ph.D.
Harold T. Shapiro Distinguished University Professor, University of Michigan

Jillian Sackler, D.B.E.
President and Chief Executive Officer, Dame Jillian & Dr. Arthur M. Sackler Foundation for the Arts, Sciences & Humanities

Lily Safra
Chairwoman, Edmond J. Safra Philanthropic Foundation

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Retired Chairman and Chief Executive Officer, Glaxo Inc.

Fred Seigel
President and Chief Operating Officer, Beacon Capital Partners

Ellen V. Sigal, Ph.D.
Chairperson, Friends of Cancer Research

Russell W. Steenberg
Managing Director and Global Head, BlackRock Private Equity Partners

Paul Stoffels, M.D.
Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Elias Zerhouni, M.D.
Professor Emeritus, Johns Hopkins University

EX OFFICIO NON-VOTING DIRECTORS

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Stephen Hahn, M.D.
Commissioner, Food and Drug Administration

EMERITUS DIRECTORS

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Chairman, Perspecta Trust

Paul Berg, Ph.D.
Cahill Professor in Biochemistry (Emeritus), Stanford University School of Medicine

Sherry Lansing
Founder and Chief Executive Officer, The Sherry Lansing Foundation

The Honorable John Edward Porter
Partner, Hogan Lovells US LLP

HONORARY DIRECTORS

Samuel O. Thier, M.D.
Professor of Medicine and Health Care Policy, Emeritus, Harvard Medical School; Member of the Center for Assessment Technology and Continuous Health, Massachusetts General Hospital

Ann Lurie
President, Lurie Holdings; President and Treasurer, Ann and Robert H. Lurie Foundation

Patrick C. Walsh, M.D.
University Distinguished Service Professor, James Buchanan Brady Urological Institute, Johns Hopkins University School of Medicine

Tab Three

NIH-FNIH Steering Committee Submissions

FNIH 25

Foundation for the National Institutes of Health

NIH-FNIH Steering Committee 2020 Submissions

The National Institutes of Health (NIH) developed a process several years ago by which projects proposed by NIH Institutes and Centers seeking the FNIH's involvement would be vetted by the Agency before transmittal to the Foundation. The final step in that process is review by an NIH-FNIH Steering Committee coordinated within the Office of the NIH Director. Below are the projects that were approved by that Committee and forwarded to the FNIH for its consideration in 2020. The FNIH conducts its own due diligence on the proposals it receives from the NIH, and projects are reviewed and potentially approved by the FNIH Portfolio Oversight Committee (POC) of the Board of Directors.

Developing Evidence-Based Music Therapies for Brain Disorders of Aging (RFC[1] received on February 11, 2020 from NIA and NCCIH): Music-based interventions show significant promise for treating symptoms of devastating disorders of aging such as stroke, Parkinson's disease, Alzheimer's disease and Alzheimer's disease related dementias, as well as for improving function during normal aging. A major limitation to more widespread application of music interventions in aging populations is the scarcity of data from rigorous, well-powered randomized controlled clinical trials. Harnessing the therapeutic potential of music is of wide interest across the NIH. The project aims to create a research roadmap for establishing more effective music-based interventions to combat disease and increase quality of life for millions of individuals suffering from neurological disorders and other conditions of aging. In April 2020, the POC approved involvement in fundraising for Phase 1 of the project (development of an NIH Toolkit), with the proviso that, due to the COVID-19 pandemic, fundraising should be delayed until the U.S. economy recovered. In October 2020, the FNIH submitted a proposal to the Renée Fleming Foundation for partial support of Phase 1. The proposal was funded in December 2020 and the FNIH transferred $60,000 to the NIH on March 12, 2021. The first of three convenings funded by the Renée Fleming Foundation's gift took place March 31, 2021.

Speech Recognition for All (RFC received on June 10, 2020 from the Clinical Center): This project aspired to create a public-private partnership between the Clinical Center and U.S. technology companies to accelerate the development of automatic speech recognition (ASR) technology for individuals with dysarthria by creating a dataset of dysarthric speech large enough to train deep learning ASR models. In August 2020, the POC identified several hurdles to successful execution of the project, including the lack of potential funders willing to support the project at the $8.3M level requested by the NIH, and suggested revisions to the RFC. The Clinical Center provided a revised proposal in October 2020, but its expectations remained inconsistent with key FNIH public-private partnership principles and the project did not move forward.

Evaluation of a Novel mRNA-based HIV-1 Vaccine in Macaques (RFC received on July 30, 2020 from NIAID): The project proposes to test a new HIV vaccine concept in animals using non-infectious "virus-like particles" encoded by an RNA vaccine with the goal of inducing protective antibody responses. In August 2020, the POC approved that FNIH proceed with the project, contingent upon a commitment of full funding in the amount of $1.45M from the Bill & Melinda

[1] RFC: Request for Collaboration from the NIH to the FNIH

Gates Foundation. The Gates commitment was received in October 2020. As of Q1 2021, the FNIH had finalized an MOU with NIAID, a sub-award with the University of Montreal (CHUM), and a service agreement with Bioqual, which will be managing the NHP trial. FNIH-generated funds have been reallocated from NIAID to Bioqual to cover the NHP costs.

Intelligent Sight and Sound (RFC received on September 4, 2020 from NCI): This study aims to create an objective measurement scale of pain from facial expression using machine learning technology, such as face and voice recognition, among a diverse set of patients with cancer who are actively undergoing treatment at an NIH clinic. As such, the primary objective of this study is to determine the feasibility of using facial recognition technology to classify pain in cancer patients who are actively undergoing treatment. A secondary objective of this study is to determine the feasibility of using voice recognition technology to transcribe patient video responses to assess pain. As of Q1 2021, Booz Allen Hamilton provided $29,568 to support patient recruitment and retention. However, NCI has since elected to cover such costs from its own budget. The FNIH is working with the company to identify an alternative use for the funds.

5 years of SABV: Moving Beyond the Policy to Advance the Health of Women (RFC received on December 18, 2020 from OD/ORWH): The Office of Research on Women's Health (ORWH) annually convenes the Vivian Pinn Symposium (VPS), its signature event, which honors the first director of the office, Dr. Vivian Pinn, and occurs in recognition of National Women's Health Week. The event is held publicly to communicate broadly about sex and gender influences on health and diseases, to disseminate research on the health of women and to highlight pressing issues in women's health research. The topic for the 2021 Symposium is "Integrating Sex and Gender into Biomedical Research as a Path for Better Science and Innovation." The event occurred on May 11-12, 2021. At ORWH's request, the FNIH provided support such as convening the Steering Committee and assisting with planning calls. Fundraising outreach occurred with $70,000 in sponsorships secured from Amgen, Myovant, Sanofi, Elsevier, and WHAM!

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Tab Four

Project Summaries

as of December 31, 2020

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Foundation for the
National Institutes of Health

FNIH 25
Foundation for the National Institutes of Health

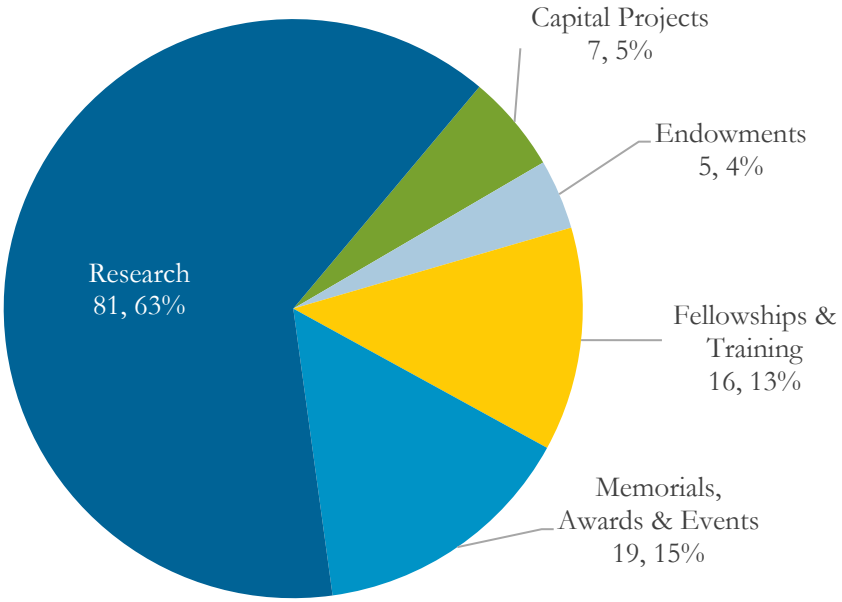
Project Summaries

as of December 31, 2020

Number of Current Projects by Activity Type

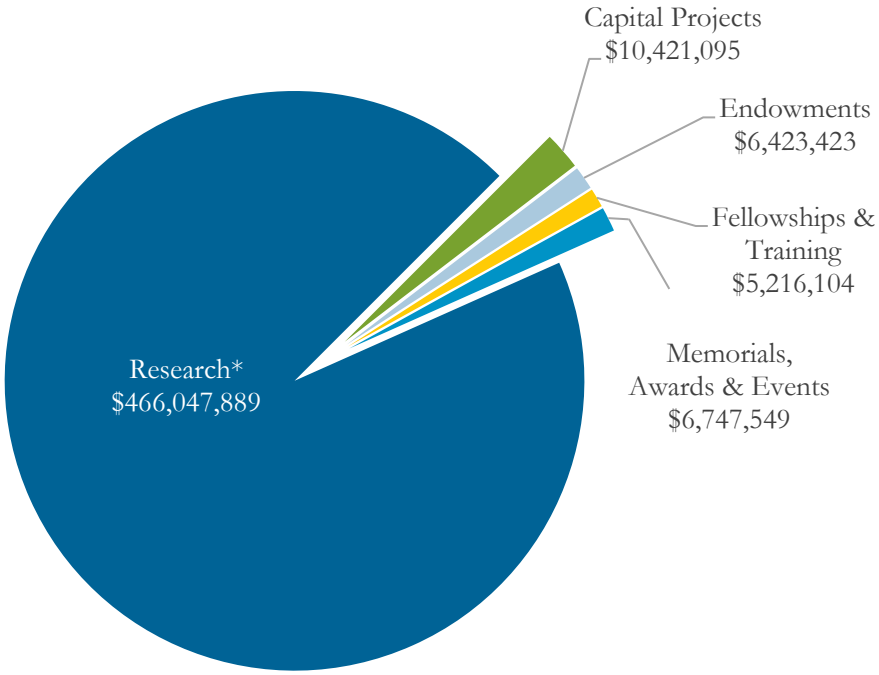
128 Projects

(Number of Projects/ Percentage of Portfolio)



Current Project Funding by Activity Type

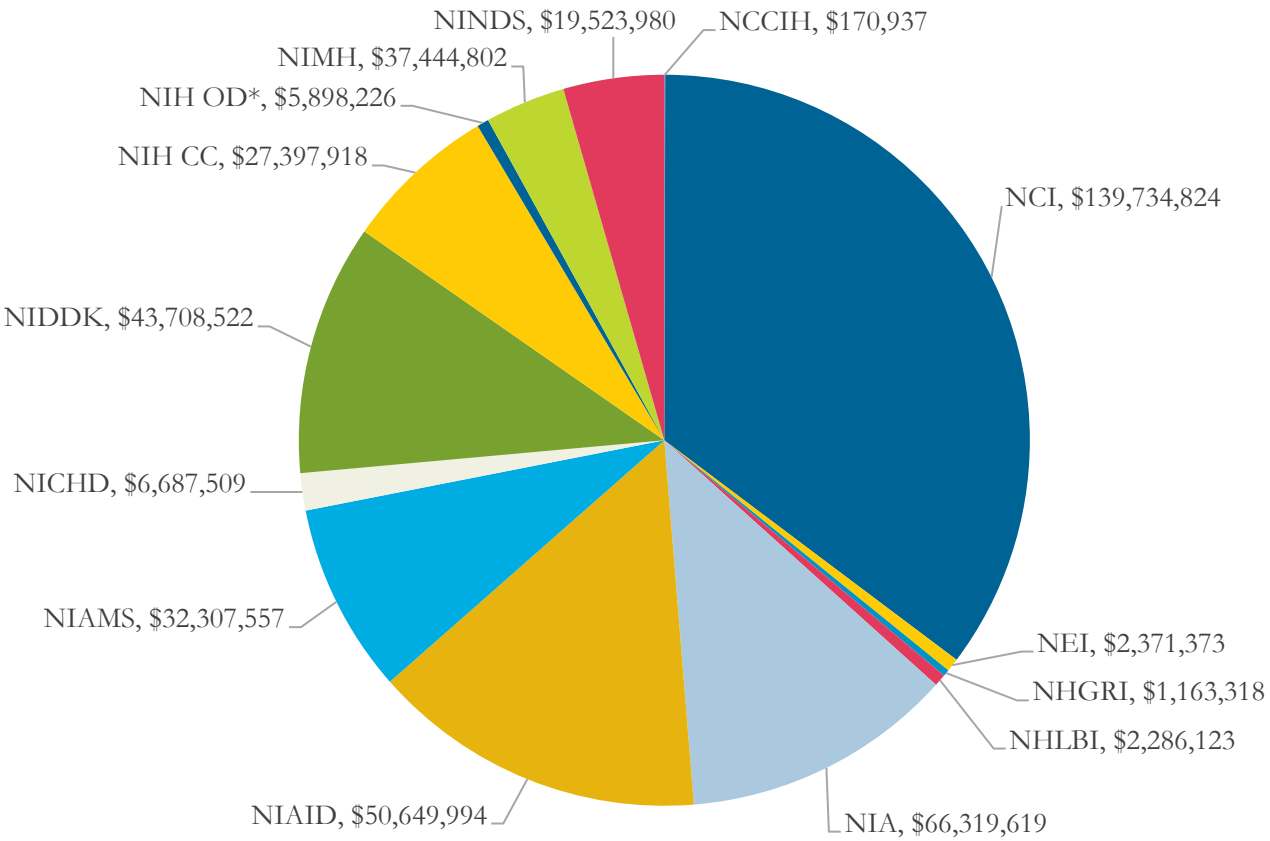
Since project inception: ~$495 million



* Includes ~$3.6 million in cash received from the USG pursuant to an Other Transactions Agreement (ACTIV) and a contract (HEAL).

Current Project Funding associated with an NIH Institute or Center

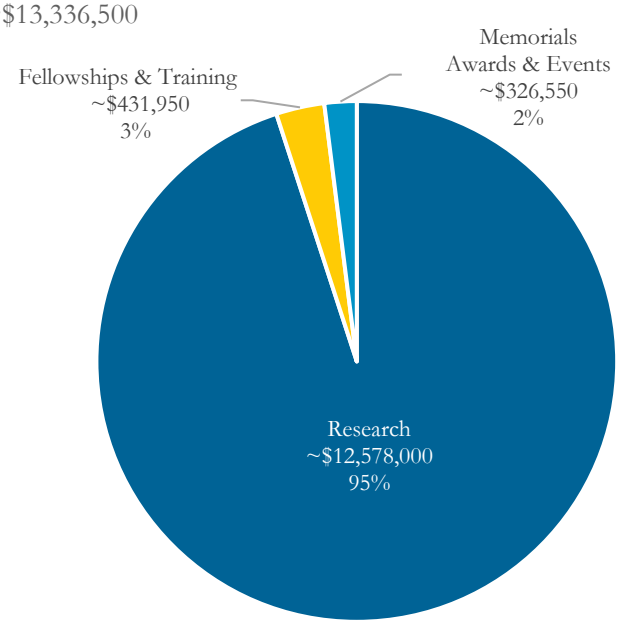
Since project inception: ~$435.5 million §



§ The remaining ~$59.5 million is not specifically associated with an Institute or Center. See "Other" Section in this Tab.

Funds Transferred to NIH by Category

Transferred in 2020: ~$13,336,500



OFFICE OF THE DIRECTOR

Office of the Director

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating COVID 19 Therapeutic Interventions and Vaccines (ACTIV)	In April 2020, the NIH, with support from the FNIH, created the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership to develop and implement a research strategy to speed development of the most promising COVID-19 vaccines and treatments. ACTIV brings together NIH with its sibling agencies in the Department of Health and Human Services, including the FDA, Biomedical Advanced Research and Development Authority (BARDA) and Centers for Disease Control and Prevention (CDC); other government agencies, including the Department of Defense and Department of Veterans Affairs; the European Medicines Agency; and representatives from academia, philanthropic organizations and 20 biopharmaceutical companies. ACTIV has developed a collaborative, streamlined forum to identify preclinical treatments, accelerate clinical testing of the most promising vaccines and treatments, improve clinical trial capacity and effectiveness and accelerate the evaluation of vaccine candidates to enable rapid authorization or approval. Six ACTIV master protocols for COVID-19 treatments are underway.	FNIH has continued to manage the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership and has had several significant advances at the end of 2020. The groups have initiated a partnership to help coordinate the collection and analysis of data on emerging variants of virus that might influence therapeutic and vaccine efficacy, continued the management of 5 master protocols to address therapeutics in out-patients, hospitalized patients, and severe patients associated with inflammatory and cardiovascular symptoms. In addition, the team continues to assess and advance preclinical and clinical assets for potential testing in all aspects of therapeutic development. Finally, the team has been addressing issues associated with vaccine treatment of pregnant and nursing women and how to measure transmission in asymptomatic infected individuals. These efforts will continue in 2021.	$3,311,507*	Apr-20
AMP-Partnership for Gene Therapy Manufacturing Technologies	The Accelerating Medicines Partnership (AMP), is a pre-competitive effort among government, academia and industry to harness collective capabilities, scale and resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases. The limited access to gene therapy, especially to populations in the ultra-rare or bespoke category, was recognized by the leadership of AMP in early 2019. Thus, we began an investigation to identify the major challenges to access and manufacturing that could be addressed in a precompetitive public-private partnership. ies. The team has identified that basic AAV life cycle biology and regulatory hurdles are areas of greatest need and largest potential impact for a partnership	Over the course of the year, a design team led by Peter Marks and Gopa Raychaudhuri (CBER) and PJ Brooks (NCATS) have worked with multiple working groups of stakeholders, and FNIH, to craft the project concept and plan for this partnership in gene therapy that focuses on the use of a single delivery vector, Adeno Associated Virus, for a generalizable process to provide more rapid access to bespoke therapies. The concept proposal was approved by the AMP Executive Committee in May 2020 and the team is now concentrated on completing a full and executable plan. Core decisions on participating vector manufacturers and disease selection for pilot clinical trials are ongoing. The program aims to have the plan completed and to initiate formal asks for support during Q4 2020.	$150,000	TBD
Helping to End Addiction Long - Term (HEAL) Partnership	HEAL is a $500M, 3-year trans-NIH research initiative to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management. FNIH has been retained by NIH under a government contract to support the operation of the HEAL Partnership Committee, a public-private group that is providing additional scientific perspective to NIH under HEAL.	The FNIH team has been working with NIH HEAL director and the institutes to develop a meeting of the HEAL partnership committee to address the biomarker needs and opportunities for advancement in pain clinical trial management. The FNIH team has helped develop the format of this meeting and is working with members of NINDS to prepare materials that will allow the HPC participants to better engage and provide actionable information for NIH to use in its own decision making processes.	$309,743*	Apr-18

* Cash received from the USG pursuant to an Other Transactions Agreement (ACTIV) or a contract (HEAL).

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
5 Years of SABV: Moving Beyond the Policy to Advance the Health of Women	The trans-NIH Strategic Plan for Women's Health Research states "innovative efforts (1) to communicate broadly about sex and gender influences on health and disease and (2) to disseminate research on the health of women in forums such as conferences and in publications are critical to accelerating scientific progress to improve the health of women." This event will serve as a forum to communicate and disseminate broadly across the biomedical enterprise on how sex and gender influences are and aren't being accounted for within research, the area of scientific opportunity the study of this presents and its impact on public health. In addition, it will garner partnerships across biomedical sectors that all have a stake in women's health research and sex/gender influences on health that can promote the integration of sex and gender considerat ions into the biomedical research enterprise.	The Office of Research on Women's Health (ORWH) of the National Institutes of Health (NIH) annually convenes the Vivian Pinn Symposium (VPS), its signature event, which honors the first director of the office, Dr. Vivian Pinn, and occurs in recognition of National Women's Health Week. The event is held publicly to communicate broadly about sex and gender influences on health and diseases, to disseminate research on the health of women, and to highlight pressing issues in women's health research. The topic for the 2021 Symposium is "Integrating Sex and Gender into Biomedical Research as a Path for Better Science and Innovation." The event will occur on May 11 - 12 and be held virtually. FNIH will seek sponsorships from a variety of prospects including Amgen, AbbVie, and L'Oreal USA, among others. The fundraising goal is $94,427. FNIH will also provide support in convening the Steering Committee and event logistics.	Fundraising efforts are underway	TBD
Oxford Cambridge Scholarship Program	NIH developed a graduate training program in collaboration with Oxford University and Cambridge University in England. Trainees spend part of their time at NIH and part at Oxford or Cambridge. The latter is the degree granting institution. The program attracts very high caliber students and NIH would like to expand it. FNIH granted FAES permission to handle this program. FNIH has agreed to handle any in-kind donations to the program.	The FNIH paid an invoice in Q2 for the 2018-2019 Oxford Cambridge Scholar Program and has not had any subsequent requests.	$174,569	Jan-04
NIH Director's Initiative Fund	This Fund was established in 2008 to honor then NIH Director, Elias Zerhouni, MD, and his vision and commitment to public-private partnerships. This Fund, established with gifts in honor of Dr. Zerhouni, allows the current NIH Director to have a pool of unrestricted funds available, managed by the FNIH, to support special initiatives not possible through other sources.	Ongoing	$38,350	Nov-08
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Amgen NIH Scholars Program	Amgen will sponsor 20 undergraduate research scholars per year for four years to participate in NIH's Summer Internship Program. The program will begin in June 2015. The Program will have four core components: 1) independent research performed under the mentorship of an NIH intramural scientist; 2) Career guidance and mentorship focused on the broad array of biomedical careers; 3) roundtable discussions exploring the intersection of research and public policy; and 4) leadership training focused on the development of skills needed to successfully work in the team-oriented global research environment.	Due to COVID-19, the Amgen Foundation has granted a no-cost extension for the Amgen Scholars at NIH Program. The FNIH and Amgen Foundation have executed an amendment which extends the grant period for a fifth year (now through 2023). The Amgen Foundation also announced it will suspend applications for a new cohort in summer 2021. Instead, institutions like NIH may accommodate deferred Scholars from 2020 with remote programming or in-person programming (to the extent possible).	1,578,823	Jun-14

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
JKTG Foundation - Post-Bacc and Graduate Intramural Research Training Fellows	The Jayne Koskinas Ted Giovanis Foundation for Health Policy (JKTG Foundation) will provide scholarship support of two young investigators in the Office of Intramural Training and Education under the mentorship of Dr. Sharon Milgram. The scholarship recipients are: Jose Delgado-Jimenez for the Postbaccalaureate Intramural Research Training Award with research interest in nanotechnology and cancer therapeutics, and Ryan Phillips for the Graduate Partnerships Program with research interest in mathematical/molecular modeling, brain circuitry and pain. A total investment of $105,210 is for first year funding of both student researchers which includes: stipend, insurance,and travel/education/research allowance.	Recruiting for IRTA award is on hold due to COVID. Review of candidates will resume in 2021.	335,235	Jun-15

NATIONAL
CANCER
INSTITUTE

National Cancer Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium -A Novel Total Lesional Automated Computerized Imaging Platform, Biomarker, and Predictive Model for Metastatic Prostate Cancer	Metastatic castration-resistant prostate cancer (mCRPC) is the second leading cause of cancer death of American men. Over 80% of these patients have metastases to the bone; for those with non-osseous spread, over 80% of soft tissue metastases are nodal. In a bone-dominant disease such as mCRPC, the lack of a surrogate endpoint for overall survival (OS) based on fully quantitative bone imaging has significantly impeded drug development and clinical care. To develop new biomarkers that can deliver a readout of a drug's activity earlier than OS, a whole-body imaging project is proposed that is non-invasive and addresses the challenges of tumor heterogeneity by capturing a patients' entire tumor burden. A multivariable response parameter will be created from the Cou302 trial database using imaging, serum biomarkers, clinical events, and progression and survival outcomes. A unique, fully quantitative response biomarker will be developed that is ready for validation in accordance with FDA guidelines for biomarker validation.	NiP officially launched on 11/1/2020. Partners include Janssen, Columbia, and MSKCC. The initial data transfer calls have begun and project team meetings will be scheduled every 6 weeks. The next Project Team Meeting is scheduled for late January and the next milestone is expected for Q4 2021.	$300,000	Aug-19
Biomarkers Consortium - Cachexia Developing Project named MARCO (Markers for Cachexia in Oncology)	Cancer associated cachexia is a systemic manifestation of diverse malignancies, and directly results in profound morbidity and higher mortality. It affects metabolic processes as well as the endocrine, immunological, and central nervous systems. It is known that cancer morbidity, mortality, and treatment toxicity increase with weight loss and myopenia. Furthermore, cachectic patients have lower treatment tolerance, resulting in poorer outcomes. Appropriate biomarkers need to be established to detect cachexia risk before patients develop overt weight loss and tissue wasting. Early detection or early prognosis would allow potential treatments to alter cachexia progression and be used to monitor ongoing therapies. With appropriate biomarkers, there is the opportunity to identify, stratify, and initiate treatment of cachectic patients earlier than in current clinical trials, optimizing the potential for therapeutic benefits. While the objective of this project is to detect cachexia early in patients with pancreatic or lung cancer—two cancers with a very high prevalence of cachexia—it is anticipated that once established, these biomarkers can be validated in cachexia of other diseases like heart failure, COPD, etc.	FNIH Development team is actively involved in seeking funds for this program.	$1,300,000	TBD

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Minimal Residual Disease in Multiple Myeloma	Past Working Groups in Multiple Myeloma have produced publications to document and clarify the role of MRD in improving patient care and enhancing the development of new therapies. The group previously described the state of the science and technology, summarized meta-analysis data of MRD on PFS and OS, and proposed studies needed to define MRD as a response biomarker/surrogate endpoint in Multiple Myeloma. The Working Group believes a guidance document would now be a valuable supplementary resource to address the specific patient sub-populations, novel therapies, and issues with capturing and reporting particular information with a level of granularity that has not been previously articulated. A guidance would support to the field to amass the data needed to replicate the first COU submission with data from other sub-populations. The guidance will note key recommendations: cut-points, time of collection, SOPs for storage and handling, and appropriate testing platforms and therapies for each patient population (newly diagnosed, post-transplant, relapse refractory and smoldering). A framework will be presented to assess available data, develop recommendations for the inclusion of MRD in prospective trials where data is needed to develop FDA submissions around the additional COUs, as well as a draft roadmap for additional FDA BQP LOIs.	The Working Group has outlined five sections of the white paper covering advances in technology and MRD measurement, regulatory considerat ions as explained by a group from FDA and a response section from industry regulatory expertise, and illuminating clinical case studies. The outline was shared with the CSC on 3/31 to wide support and provided to the EC for their review and comment on 5/22. Drafting amongst subsections started in Q2 2020. All sections are complete including clinical case studies across 4 patient populations, a technology review and and FDA-provided regulatory perspective. The final draft was reviewed by the entire group and updates were made to an accompanying MM trials roster. The final draft is with the co-chairs for final review and submission for publication in Q1 2021.	Fundraising efforts are underway	TBD
Biomarkers Consortium - Chemotherapeutic Impact on the Immune MicroEnvironment	The clinical impact of tumor immunity in patients with cancer is variable and many patients fail to respond to immunotherapy (IO). One hypothesis for nonresponse is differential regulation of factors in the immune microenviroment (ME). Therefore, there is a need to study the ME before, during, and following therapy, to inform how to sequence and combine IO and chemotherapy and to discover new biomarkers and effective interventions. This project will use single nucleus RNA-seq (sNuc-Seq), pioneered by the Klarman Cell Observatory (KCO) at the Broad Institute, to define the heterogenous state of malignant and non-malignant cells in the tumor ME (TME) from patients undergoing clinical care. Tumor samples will be collected from the Dana Farber Cancer Institute and the Howard Hughes Medical Institute. Results could lead to therapeutic hypotheses for IO, identification of novel biomarkers, improvements in drug development, and better patient stratification.	Under the leadership of PI Nick Wagle, ChIIME team met on 10/26/2020 to discuss the updated timetable. All funding partners agreed to extend the contracts to account for the COVID delays. The updated timeline includes a new Pilot Project Completion Date of mid-March. The Project Team will meet in February to discuss the project's progress and then will meet in mid-March to review the Pilot Project results and vote on the go/no-go milestone. At this time there are no additional expected delays and Broad is on schedule	$1,957,386	Apr-18

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Developing an Analytically and Clinically Validated Reference Material for ctDNA Testing	Liquid biopsies are widely recognized as a key component to fully realizing precision medicine. The most widely used circulating biomarker today is circulating tumor DNA (ctDNA). There are no universally recognized reference materials however that allow laboratorians, physicians, regulators, or payers to determine if all the processing steps worked correctly, and the results are accurate. The ctDNA Quality Control Material project seeks to develop processes to enable the production of QC materials in partnership with commercial reference material manufacturers for widespread use in liquid biopsy testing. Successful development and dissemination of QC material that can be used to establish the analytical validation and accurate interpretation of clinical assays will provide the scientific and healthcare community confidence in interpretation of ctDNA biomarker assay results in clinical research, therapeutic decision-making, regulatory evaluation, and reimbursement.	The ctDNA Quality Control Materials Project Plan was presented to the CSC on 6/26/18 and received approval from the EC on 8/16. The final budget of $1,238,575 reflects in-kind contributions of $1million and an estimated $500K for the phase 3 clinical study. FNIH executed 3 agreements with reference material manufacturers to transfer QC materials with 14 variants identified and refined through in-person meetings 3/20/18 and 4/16/18, and in discussions with the FDA 3/26 and 7/5. Funding agreements with 5 companies, 2 RCAs, 1 CRADA with the central lab and 1 MOU with NIST were executed and the project officially luanched 9/24/19. Additional discussions with FDA were held 4/6, 8/20 and 9/28/20 to inform the Phase 2 Functional Characteri zation study and Phase 3 Clinical pilot design. Initial performance evaluation data was reviewed with the manufacturing companies and the full project team, and the manuscript was submitted for publication in Q4 2020 to JCO-Precision Oncology. Phase 2 CSFC study is set to begin Q1 2020 with additional funds allocated to two sites and accompanying contract modifications underway. 15 donated services agreements are in development, 8 executed, for external labs to perform phase 3 clinical testing, set to begin Q3 2020.	$1,551,918	Apr-18
Biomarkers Consortium - Vol-PACT: Advanced metrics and modeling with Volumetric CT for Precision Analysis of Clinical Trial results	Volumetric CT for Precision Analysis of Clinical Trial Results (Vol-PACT) is a collaborative research partnership collecting imaging data and associated clinical data from large, completed Phase II/III RCTs in several measurable solid tumors. The aim is to comprehensively study metrics in the context of unidimensional, bidimensional, and volumetric tumor measurements in their ability to predict clinical outcomes. Preliminary simulation results were produced in a Pilot study using data from Sanofi's VELOUR and GSK / Novartis COMPARZ trials. Data from ten total trials has been secured, with three additional trials promised, including renal cell carcinoma, colorectal cancer (CRC), lung cancer, and melanoma. Trial data sets include both targeted and immunotherapy treatments, and the team will be synergizing efforts with the EORTC and RECIST committees.	Vol-PACT is the Phase 2 extension of the Vol-PACT Pilot project, retained the same core team and launched January 2017. Two additional companies contributed in 2017 making 7 committed funding partners for 3 years. A Project Plan Addendum provides for deeper analysis of IO response metrics, including standardiz ation of iRECIST. At the request of the sponsors, the project team developed a radiomics and modelling pilot for an additional $800,000 in funding and contract amendments were executed. The Project Plan reflects the updated number of clinical trials targeted for analysis (12) and corresponding budget ($3.6M). 5 lead metrics were identified in the first annual report and a go/no-go decision at 1.5 years was passed unanimously. A second annual report described the split of training and validation data sets for analysis of time-depen dent, kinetic and radiomic modelling metrics. A CRC methods case study and iRECIST comparison paper were published in Q3 2020. A radiomic modelling in melanoma manuscript was published in Q4 2020 and three additional manuscripts are in drafting to highlight use cases of the final models. The team approved a NCE to close out the project 12/31/20 though the team continues final analyses for publication and preparation of a concept proposal and data requests for a phase 3 project into 2021.	$3,601,000	Jan-17

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Bradley Charitable Gift Annuity	The Bradley family has made a $250,000 charitable gift annuity to the FNIH in support of Dr. Staudt's lab or his successors to support lymphoma and leukemia research at the NCI. In accordance with the gift annuity rates set forth by the American Council on Gift Annuities (used by most charities in their issuance of gift annuities), the FNIH is obligated to pay the family 4.6% annually, or $11,500, every year until the survivor of them dies, at which time the remaining amount reverts to the FNIH to fund the project. The FNIH will then retain 5% of the remaining amount of the annuity and transfer 95% of the remaining amount to Dr. Staudt's laboratory or his successors.	FNIH staff provided a stewardship report to the Bradleys from Dr. Louis Staudt, NCI, on Follicular Lymphoma research.	$250,000	May-12
BRCA Challenge Fund	The BRCA Challenge is based on shared data from clinicians, clinical laboratories and researchers across the world, all with the intention of improving the precision of interpreting variants identified in clinical testing of BRCA1 and BRCA2. API for all to use on smartphones to query clinically determined variants. Inherited variation in the BRCA1 and BRCA2 genes can indicate genetic predisposition to breast, ovarian and other cancers. Since the large majority of BRCA1 and BRCA2 variants are not pathogenic, there is great need to develop a comprehensive data resource for collecting, annotating and interpreting variation across both genes. The Division of Cancer Epidemiology and Genetics is co-leading the effort to develop a resource that will be a comprehensive repository of BRCA variation, linking current structure and resources while encouraging deposition of new data.	FNIH staff steward the donor as they considered continuing supporting this program.	$32,450	Jan-18
Cancer Research Fund	As a part of its outreach efforts to individuals who may be interested in supporting NIH and, more specifically, the work of NCI, this fund was established to hold contributions received to support cancer research. Contributions may be designated simply for "cancer research" or, if desired by the donor, for more targeted initiatives underway at NIH. The Foundation will work with NCI to determine how this growing pool of general funds might best be applied whether through fellowships, as project seed funding, or through another mechanisms.	FNIH Staff continues to receive support for this fund.	$2,511,513	Feb-00
Cancer Steering Committee Annual Scientific Symposium 2020	Each year, the CSC brings together experts from academia, pharmaceutical companies, biotechnology companies, not-for-profit organizations, the NIH and the FDA to participate in this symposium to review advances in the field of biomarker and regulatory science that are relevant to the development of new public-private partnerships for precompetitive biomarkers. The CSC Scientific Symposium thus serves as an opportunity each year to assess and recalibrate future directions in biomarker discovery and development. Topic areas covered include analytical validation and clinical utility of liquid biopsy, project opportunities around immuno-oncology biomarkers, cross-disease analysis of biomarker initiatives in the microbiome, and Minimal Residual Disease in blood-based cancers.	The 2020 CSC Symposium was a fully virtual event that utilized the new BoomSet virtual meeting platform.We fully funded the Symposium through sponsors including Pfizer and Adaptive Technologies (Gold Level at $25,000), JnJ (Silver Level at $10,000), and Bayer, Genentech, Genmab, Sanofi (Bronze Level at $5,000). The final invitation list included members of all project teams and working groups, bringing the new total of potential attendees to 430+. The meeting was well attended with over 200 unique attendees joining at least one session. Feedback from the attendees was almost entirely positive. Planning is underway for the 2021 CSC Symposium.	$85,400	Nov-20

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Efficacy of heterodimeric IL-15 treatment regimens in reducing SIV reservoir	This project evaluates the ability of a heterodimeric form of the cytokine IL-15 and the IL-15 receptor (hetIL-15) to flush-out and kill HIV/SIV-infected cells that serve as virus reservoirs in in infected rhesus macaques (RM) on long-term antiretroviral therapy (ART). The program pulls together the expertise of collaborators from the University of Louisiana Laffite, Case Western Reserve University, the Vaccine Research Center at NIAID/NIH and the National Cancer Institute. RMs will vaccinated with a DNA-based vaccine followed by DNA/protein boost and either treated with hetIL-15 as single agent or in combination with a PD-1/PD-L1 check-point inhibitor. A passive immunization strategy with an SIV neutralizing antibody will be considered depending on reagent availability. The work will help elucidate mechanisms for establishing and disrupting viral reservoirs established during HIV infections while also exploring treatments with the potential of clearing the virus or controlling virus rebound to eliminate the need for antiretroviral regimens and/or eliminating the risk of further transmission of the virus	With only minor setbacks due to COVID-19, the science reveals the gradual progress and timely completion of the NHP trial. The year 4 annual report will detail their progress and be submitted at the end of January 2021.	$2,874,832	Dec-16
Follicular Lymphoma Research Fund	Mr. Andrew Feinberg has made a $100,000 pledge of support for five yearly installments of $20,000 to the laboratory of Dr. Wyndham Wilson and NCI colleagues, who are developing a research project to further understand the biology of follicular lymphoma. The project titled, "Use of functional genomics to define new therapeutic strategies in transformed follicular lymphoma" has two specific aims: 1.) Identify essential genes in cell line models of tFL using CRISPR-based genetic screens. 2.) Specific Aim 2: Identify genes that confer sensitization or resistance to BCL2 inhibitors in tFL.	FNIH staff provided stewardship reports to the donors of this project. The report described the current work and accomplish ments of follicular lymphoma research through gene research.	$117,500	Nov-15
Gramlich Melanoma Research Fund	The Gramlich Melanoma Research Fund supports melanoma research at NIH through an annual gift provided by the estate of Jack Gramlich.	FNIH Staff continue to steward this fund. FNIH staff reached out to confirm the annual distribution before year-end.	$450,075	Jun-08
Intelligent Sight and Sound	The ISS study aims to create an objective measurement scale of pain from facial expression using machine learning technology, such as face and voice recognition, among a diverse set of patients with cancer who are actively undergoing treatment at an NIH clinic. Goals: The primary objective of this study is to determine the feasibility of using facial recognition technology to classify pain in cancer patients who are actively undergoing treatment. A secondary objective of this study is to determine the feasibility of using voice recognition technology to transcribe patient video responses to assess pain. □	Led by the National Cancer Institute (NCI), the overall purpose of the Project is to create an objective measurement scale of pain from facial expression using machine learning technology, such as face and voice recognition, among a diverse set of patients with cancer who are actively undergoing treatment at an NIH clinic. The overarching goal is to help patients experiencing pain related to cancer treatment.	Fundraising efforts are underway.	TBD
Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.	Dr. Linehan's laboratory personnel are working to develop novel approaches targeting kidney cancer gene pathways, and evaluating these agents in patients treated at the NIH Clinical Center. Their studies of the different types of kidney cancer have demonstrated that it is fundamentally a metabolic disease. Both in the laboratory and in the clinic, they are evaluating new agents targeting the metabolic pathways in kidney cancer—for patients with clear cell kidney cancer, von Hippel Lindau disease, sporadic (non-hereditary) papillary kidney cancer, papillary kidney cancer, Hereditary Papillary Renal Cell Carcinoma, Renal Cell Carcinoma, and Hereditary Leiomyomatosis— and are very encouraged about the results of these studies, which promise to build on Dr. Linehan's great legacy of finding new therapeutic approaches for patients with kidney cancer.	FNIH staff stewarded Driven to Cure's efforts to fundraise for HLRCC research during this pandemic.	$787,850	Nov-13

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer	Lung-MAP (launched in 2014) is a groundbreaking clinical trial model that uses a multi-drug, targeted screening approach to match patients with sub-studies testing investigational new treatments based on their unique tumor profiles. Patients who enroll in Lung-MAP get a state-of-the-art genomic profile to determine the genomic alterations, or mutations, which may drive the growth of their cancer. Based on those results, patients are matched to a treatment being tested on Lung-MAP. If there isn't a genomic "match" patients have an option of receiving immunotherapy treatments used in the trials. The trial has also been redesigned to include a non-match study that treats patients with a randomized immunotherapy regime. In 2018, the trial was significantly expanded to include patients with all advanced non-small cell lung cancers (NSCLC), meaning it's now opened to even more patients with lung cancer who will have access to investigational treatments to fight their disease. This new expansion now falls under the new screening protocol, LUNGMAP, (previously called S1400).	The Lung-MAP trial was activated on 6/16/14. A major revision took place on 12/18/16, after FDA approval of Opdivo (BMS). As of 7/20/2020, 1391 patients have been registered /screened under the new LUNGMAP screening protocol (1864 patients were registered under S1400 (from June, 2014 to January, 2019), prior to LUNGMAP being activated). Current active sub-studies are: S1900B (2/10/20). S1400A and E were closed at company request. S1400B, C, D, I, G, and K were completed after interim analysis due to lack of patient response on 12/5/16, 9/1/16, 11/1/16, 4/23/18, 7/23/18, and 11/15/18 respectively. S1400F closed on 3/24/20 due to feasibility. S1400GEN was completed in 06/2019, and the findings were presented at WCLC 2019. S1900A closed (effective 2/1/21) due to futility. S1800A and S1900C completed accrual and both closed on 12/18/20. CTEP provided an approval (7/16/18) for a new LUNGMAP screening protocol which activated on 1/28/19, expanding the trial to all NSCLC histologies, IO combinations for anti-PDL-1 refractory patients, and inclusion of a ctDNA liquid biopsy screening. Lung-MAP is negotiating with 2 companies for new sub-studies. One new study is to open in February 2021 (Amgen) and one estimated for Q3 2021 (ImmunityB IO). FNIH continues to support meetings for the Policy, Trial Oversight, Accrual Enhancement, and Drug Selection committees. A governance committee restructure was established to be more inclusive of all NCI cooperative groups, update the appropriate committees, assign committee chairs, revise membership, and set meeting cadence for each.	$59,159,640	Jun-14
NCTN Data Archive De-Identification Project	The NCTN Data Archive is an NCI database of individual-level data from clinical trials conducted by the National Clinical Trials Network that is broadly available for access by the entire scientific community on a controlled basis. To enable such broad sharing, the data must be de-identified, formatted and accompanied by data dictionaries. The seeks funding from the private sector support the de-identification and data preparation process to allow these datasets to become available to the public and scientific researchers more quickly than would otherwise be possible.	Currently 23 Phase 3 Clinical Trial datasets have been selected by the NCI for de-identif ication, including data from approximately 34,000 patients. The FNIH transferred $230,00 to NCI in April 2019 to cover de-identif ication costs for the 23 datasets; de-identif ication is currently underway and data are being uploaded. Through Q4 2020, 19 of the 23 datasets with data from approximately 30,000 patients are now available to the public and scientific researchers that previously were not. The estimated total project budget is $683,953, of which $420,000 has been raised to date. The FNIH is actively exploring additional support for the project and sending updates on the project to the current funding partners.	$420,000	Sep-16

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Partnership for Accelerating Cancer Therapies - Implementation Phase	Recent cancer treatment success is driven by new immuno-oncology (IO) agents, leading large investment in the field. However, improvements in outcomes generated by the single agents are possible only for a minority of patients, and emerging data demonstrate the greatest impact on cancer treatment will be through combinations of agents both IO and non-IO. Successful pursuit of combination therapies is complicated by the sheer number of possible combinations, high biologic complexity, and the need for new translational biomarkers to guide patient treatment. To solve these challenges, a systematic cross-sector effort is required develop robust, standardized biomarkers to support selection and testing of combinations. The Partnership for Accelerating Cancer Therapies (PACT) is a 5-year collaboration totaling $220 million launched by the NIH/NCI, the FNIH, and 12 leading pharmaceutical companies (AbbVie, Amgen, Boehringer-Ingelheim, BMS, Celgene, Genentech, Gilead, GSK, Janssen, Novartis, Pfizer, and Sanofi) as part of the Cancer Moonshot. PACT will focus on efforts to identify, develop, and validate robust biomarkers "standardized biological markers of disease and treatment response" to advance new IO treatments. The partnership will be managed by the FNIH. The FDA and patient advocate(s) will serve in an advisory role.	The Fall Joint Meeting of the PACT JSC and CIMAC-CIDC Network was held virtually 11/9-11/10 /2020 via the Boomset Virtual Meeting Platform. A joint planning committee, with members from both PACT and the CIMAC-CIDC Network, worked diligently to plan a thoughtful and productive agenda for this virtual meeting, which was very successful. To date, a total of 7 clinical trials have been approved for PACT funding of correlative biomarker work, with additional trials in development. SOWs for three trials have been finalized and executed, with HMTAs for two trials executed. SOWs and HMTAs in process for the remaining trials. No Cost Extensions for a subset of current contracts are in stages of considerat ion, development, and execution due to the delays encountered by both the CIMAC-CIDC Network and the Novel Biomarker RFA awardees as a result of the COVID-19 pandemic. The 2nd annual IO Novel Biomarker RFA webinar is scheduled to be held 3/2/2021 and will feature presentations from the awardees of the first RFA, and all members of PACT and the CIMAC-CIDC Network have been invited. The second Novel Biomarker RFA was finalized and is projected to be released 1/29/2021. Applications will be accepted until 3/31/2021. The next annual PACT Report, generated by the CIMAC-CIDC Network for the PACT governance committees documenting the work done in the third year of the project, is being prepared and will be finalized prior to the 1/31/2021 deadline.	$60,367,865	Feb-18
ACT4PEDS (formerly Predevelopment Pediatric Oncology)	The overall purpose of this design phase is to develop a viable PPP that will generate preclinical data to inform prioritization decisions about new anti-cancer agents considered potentially relevant to the growth or progression of one or more childhood cancers and to disseminate these data to all appropriate stakeholders. Results from the PPP may be used by regulatory agencies, biopharma companies, and academic researchers to inform decisions about which agents to clinically evaluate for specific childhood cancers to address the provisions in the FDA Reauthorization Act (FDARA) of 2017. Title V of FDARA amended the Pediatric Research Equity Act (PREA) to require “molecularly targeted pediatric cancer investigations”, defined as clinical studies designed to yield clinically meaningful pediatric study data regarding dosing, safety and preliminary efficacy to inform potential pediatric labeling. The design and development of the PPP will be a collaboration with National Institute of Health, multiple biopharmaceutical companies, FDA, research foundations, philanthropies, and the FNIH.	On 4/12/19 an RFC was received from NIH to ask for FNIH's assistance with the design effort for this project. The FNIH Board PPP committee reviewed and approved this proposal on 4/23/19. PhRMA provided contributions of $200,000 and $180,000 to support the Design Phase. To begin, FNIH conducted 40+ introductory and working group calls with members of pharmaceut ical companies, NCI, FDA, nonprofits, and other preclinical pediatric organizati ons. Information from these calls was parlayed into a 2-day in-person facilitated design session meeting on 9/5-9/6/19, which built consensus and helped finalize the design of the potential public-pri vate partnership. The FNIH assembled writing teams and generated a first draft of the white paper. After receiving and reviewing comments by all stakeholders, the final white paper was released in March 2020. NIH BSA approved $29.5 million for preclinical pediatric in vivo testing as public contribution to the partnership in May 2020, and 1.7M was put by CCDI towards the developments of Data Commons. In June 2020, FNIH started reaching out to all stakeholders to support implementa tion of the full partnership as designed. COVID-19 caused delays and reshaping of funding priorities for many stakeholders, with ripple effect felt in FNIH’s current funding outreach for this project. Relying on a strong support of FDA, NCI, and pediatric oncology advocacy community we will continue approaching the companies to facilitate their engagement in the partnership in early 2021, but understanding that adjustments to the plan may be needed in order to launch this important partnership.	$380,100	Jun-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Stephen J. Solarz Memorial Fund	The Solarz Fund supports research in the laboratory of Dr. David Schrump at the National Cancer Institute. The Solarz Fund has raised over $304,000 since it was established in 2010. Funds have supported costs associated with Dr. Schrump's research using molecular biological techniques to manipulate DNA in cells taken from a patient's tumor to produce molecules that will stimulate the patient's immune system to kill cancer cells. Funds to also be used in support of International funding opportunities of post-doctorate scientists/researchers in the field of cancer.	FNIH staff sent communications to check in and provide updates during this pandemic. FNIH staff also supported Nina Solarz in her efforts to establish an international lab under the supervision of Dr. David Schrump, NCI.	$678,757	Nov-10
The Lowy Cancer Research Support Fund	Funds are for the discretionary purpose of Dr. Douglas Lowy, Acting Director of the National Cancer Institute to provide support to cancer program activities. These activities could include events, meetings, etc. which might include refreshments, travel or other support.	The FNIH supported the Rabson Memorial reception with these funds in partnership with the NCI.	$22,500	May-15
TLR Ligand Augmented, Tissue Homing AIDS Virus-Specific Adoptive Cell Therapy to Target Viral Reservoirs	The study will evaluate an approach to target and reduce or eliminate persistent virus-infected T follicular helper cells (Tfh) in lymphoid tissue. Persistent virus infection of this cell type is thought to be an important component of the overall viral reservoir in HIV-infected individuals. The essential properties of this reservoir are recapitulated in rhesus macaques infected with a simian equivalent of HIV, designated Simian Immunodeficiency Virus (SIV). This study will characterize the role of persistent-infected Tfh cells in maintaining the viral reservoir in the most authentic animal model available. Furthermore, the study will provide a proof of concept for a promising immunotherapy approach to target this reservoir to achieve a more definitive treatment of HIV infection, and will have clear clinical translation possibilities.	Due to COVID-19 impacts on the availability of rhesus macaques, the research workplan may be impacted. The FNIH is monitoring the situation and assessing whether an extension request may be warranted.	$1,979,348	Jan-18
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Adam Berry Memorial Fund	The Adam J. Berry Memorial Fund was established by Michael and Sue Berry in memory of their beloved son, Adam. Adam came from Australia to work as a research scientist at the National Cancer Institute at NIH. The fund commemorates his life and his enthusiasm for work by making it possible for promising young Australian scientists to travel to the United States and work at NIH.	Kate Secombe was selected to receive the Adam Berry Travel Award to train at NIH. However due to limitations in international travel, the training has been suspended as well as announcements for the next award until 2021.	$23,947	Jan-03

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Anita Roberts Memorial Fund	Dr. Roberts was one of the first woman laboratory chiefs at NIH and ranked in the top 50 most-cited biological scientists in the world. She was widely recognized as an outstanding mentor, encouraging and inspiring young scientists. In recognition of her commitment to mentoring, Dr. Roberts' family and lab colleagues established scholarships to allow graduate students and post-doctoral fellows to present their work at a national meeting. Two travel scholarships are awarded to the TGF-beta Keystone Symposium held every other year. These scholarships are a fitting tribute to Dr. Roberts' passion for encouraging the career development of young scientists.	FNIH staff held a meeting with Dr. Bob Roberts to check in and provide updates.	$60,628	Jun-06
Jerry D. Jennings Memorial Fund	The fund honors the father of Catherine Jennings Davis who died of renal cell cancer in July 2006. The Jennings Family funds go to support renal cell cancer research at NIH.	The donors have expressed interest in supporting the purchase of a device to help in renal cancer research needed by the laboratory of Richard Childs of the NHLBI. FNIH met with Dr. Childs to discuss the donors' interest and to identify additional areas of renal cell cancer research that could be supported through these funds. Harris to follow up with the Jennings Family.	$3,980	Sep-06
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
NCI Neuro Oncology Branch Fund	The Neuro-Oncology Branch (NOB) is a trans-institutional initiative in neuro-oncology sponsored by both NCI and NINDS that launched in 2000. NOB's mission is to develop novel diagnostic and therapeutic agents for patients with primary central nervous system tumors. They are building a biology-driven, individualized, patient-centric, rational therapeutics program. The NOB receives donations from patients, their families and friends, and others to support their research and would like to establish a fund at FNIH to hold such donations.	FNIH sent the Schatzkin Lecture speaker honorarium to Dr. Michael Leitzmann and forwarded it to NCI.	$30,057	Mar-11
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Sallie Rosen Kaplan Fund for Women Scientists in Cancer Research	The Kaplan Fund provides annual support for the Sallie Rosen Kaplan Fellowships for Women Scientists in Cancer Research. These post-doctoral fellowship awards are given annually to 10 outstanding woman scientists at the National Cancer Institute.	NCI and FNIH staff submitted the end of year report to Dr. Rosen, the estate executor. The report commented on the accomplishments and challenges this year due to COVID-19, and looked forward to the next year and new cohort of postbacs.	$788,081	Jan-99

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

National Center for Complementary and Integrative Health

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Stephen E. Straus Distinguished Lecture in CAM	Established by Bernard and Barbro Osher in 2006, this fund honors the late Dr. Stephen E. Straus, the founding director of NIH's National Center for Complementary and Integrative Health (NCCIH). It supports the Stephen E. Straus Distinguished Lecture in the Science of Complementary and Alternative Medicine, an annual lecture that brings leading figures in science and medicine to NIH to speak about their perspective on the field of complementary and alternative medicine. Open to the public, the lecture is videocast and archived on the NCCIH website.	The next annual Stephen Straus Distinguished Lecture took place December 9. 2020 with featured speaker, Dr. Shannon Zenk, Director, NINR. Following the lecture was a distinguished virtual roundtable with fellow NCCIH and NIH staff, among others.	$170,937	Jan-07

NATIONAL
EYE
INSTITUTE

National Eye Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Age-Related Eye Disease Study 2 (AREDS2) Ancillary Study	The Age-Related Eye Disease Study (AREDS) was a major clinical trial designed to learn more about age-related macular degeneration (AMD) and cataract and to evaluate the effect of certain vitamins and zinc on the progression of AMD and cataract. Results showed that high levels of antioxidants and zinc significantly reduce the risk of advanced AMD and its associated vision loss. These same nutrients had no significant effect on the development or progression of cataract. In May 2013, the NEI completed AREDS2, which tested several changes to the formulation and found that while omega-3 fatty acids had no effect on the formulation, lutein and zeaxanthin together appeared to be a safe and effective alternative to beta-carotene. Funds raised by FNIH support development of a follow-on genetic study and analysis.	For the genetic study, funds raised by FNIH enabled NEI to collect DNA on 2,025 participants in AREDS2. A funding balance remained at the close of the study. In 2017 NEI indicated that further genetic testing and work was planned. A 10-year follow-on study was designed to examine the long-term effects of oral supplements of lutein and zeaxanthin and omega-3 long chain polyunsatu rated fatty acids (LCPUFAs) on the incidence of lung cancer, development of late age-related macular degeneration (AMD), cataract surgery, cognitive function scores, and incident cardiovasc ular events. To support the study, the FNIH transferred the final balance of $381,764 to the NEI in November 2017. Data collection was completed in late 2018. NEI is working on a 10-year follow-up, and a publication is expected soon.	$990,005	Apr-10
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Dr. Jane M. Sayer Vision Research Lecture & Award	The Sayer Vision Research Fund supports the annual Sayer Lecture delivered by an investigator in the area of vision research. The fund also supports the Sayer Vision Research Award, a grant-in-aid to support the research of a promising independent investigator in the early stage of his or her research career in the Division of Intramural Research at the National Eye Institute.	The Sayer Vision Research Lecture and Award was scheduled to take place on April 21, 2020, however was cancelled due to COVID. The featured speaker was to be Dr. Kapil Bharti, NEI. A date has not yet been determined for rescheduling.	$381,368	May-20
Joram Piatigorsky Basic Science Lecture and Award	The aim of the Lecture and Award is to bring attention to notable basic science contributions by vision and eye scientists to a diverse general scientific audience, like molecular biology, genetics, developmental biology and computer science. This differs from the more common research themes in eye biology, vision and ophthalmology, which emphasize discoveries in the general sciences that have led to advances in eye biology and medical treatments.	FNIH staff discussed the prospect of holding a virtual or in-person event in 2021. And continued to steward and develop a plan for the inaugural meeting.	$1,000,000	Sep-20

NATIONAL
HUMAN
GENOME
RESEARCH
INSTITUTE

National Human Genome Research Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Genome Research Fund	As a part of its outreach efforts to individuals who may be interested in supporting NIH and, more specifically, the work of NHGRI, this Fund was established in January 2013 to hold contributions received to support genetics/genomics research. Contributions may be designated simply for "genetics or genomics research" or, if desired by the donor, for more targeted initiatives underway at NIH. The Foundation will work with NHGRI to determine how this growing pool of general funds might best be applied whether through fellowships, as project seed funding, or through another mechanism.	No recent activity.	$2,735	Oct-11
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Human Genome Exhibition	In June 2013, the National Human Genome Research Institute (NHGRI) and the National Institutes of Health (NIH), in partnership with the Smithsonian Institution, celebrated the 10th anniversary of the sequencing of the human genome and the 60th anniversary of the Watson-Crick discovery of DNA's structure with a major exhibition initiative, Genome: Unlocking Life's Code, at the National Museum of Natural History. Through high-tech, hands-on interactive activities and educational programming, Genome celebrates the advances related to the sequencing of the human genome, and helps make genomics accessible, understandable, and exciting to the general public. More than just an exhibition within the walls of the Museum, the project includes a large-scale, multi-platform educational effort that is communicating how genomic science, and the era of personalized medicine is playing, and will continue to play, a critical role in our everyday lives and health care.	GENOME: UNLOCKING LIFE'S CODE September 21, 2019 - January 2, 2020 Turtle Bay Exploration Park 844 Sundial Bridge Drive Redding, California 96003 https://www.turtlebay.org	$1,155,000	Oct-11
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
The NIH Undiagnosed Diseases Program	The UDP diagnoses patients who have long been unable to find any diagnosis, to discover new disorders that will provide insight into biochemical and cell biological pathways, and to bring genomics to modern medicine, especially in the area of rare diseases. It fosters personalized medicine. The FNIH would serve as a conduit for donations of funds and services; i.e., in-kind such as software packages and expertise.	FNIH continues to include the Undiagnosed Disease Program (UDP) among the programs it discusses with potential donors who may find it to be of interest.	$5,583	Sep-11

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

National Heart, Lung, and Blood Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Heart Failure	The Accelerating Medicines Partnership (AMP) in Heart Failure is a multiple-sector, pre-competitive partnership whose goal is to harness trials data and knowledge from Heart Failure clinical trials at scale in order to deconstruct Heart Failue with Preserved Ejection Fraction towards better understanding of the disease.	FNIH welcomed NHLBI and 11 pharmaceutical companies to a kickoff meeting on Nov 9, 2020. Since then, FNIH is managing the design phase for AMP in Heart Failure through 6-8 meetings every month. A white paper outline has been developed and will be finalized by Q2 2021.	$120,000	TBD
Biomarkers Consortium - Novel Cardiac Biomarkers in the General US Population	The main goals of the Cardiac Troponin Biomarker Project are: 1) to define the reference ranges for novel cardiac biomarkers (BM) in a young healthy subgroup of adults and to describe the normal BM variation; 2) to characterize the cross-sectional associations of these novel BMs with other novel diabetes, kidney disease and cardiovascular disease risk BMs and 3) to characterize their associations with total mortality while comparing them head to head in their effectiveness for mortality risk prediction. The project will conduct a comprehensive national study, utilizing existing stored blood and urine specimens and data from NHANES (NCHS,CDC), providing key reference data and informing recommendations and clinical guidelines regarding the use of these BMs. The Cardiac Troponin project plan was approved by the Metabolic Disorders Steering Committee in late 2013 and by the Executive Committee in June 2014.The project was launched in January 2016 and is scheduled to complete by January 202	The investigators have collaborated with statisticians at the CDC/NCHS to finalize the pull-list and to identify the specimens from The National Health and Nutrition Examination Survey (NHANES) repository that will be retrieved for the project. The UMD laboratory has received all testing reagents. Due to unforeseen challenges (laboratory fire followed by some sample shipment discrepancies), the testing has been delayed. UMD Labs have received all samples and analyzed ~4500 of the ~25000 samples.Data sharing agreement was signed with NCHS and merging of de-identified NCHS data files is completed. A QC analysis in pooled samples demonstrated the high reliability and validity of all laboratory test analytes with concentrations falling within expected range. Transfer of final laboratory test result files to JHU and the successful linkage of final data files to mortality follow up data from the National Death Index, is currently in process. The team has received presently a total of 2,500 samples. Given this increased sample load and delay in start up, the Project Team has granted a NCE until April 2021. A F2F Project Team meeting was held in November 2019 in Philadelphia as a side bar conversation to the AHA. The team discussed next steps for the last 15 months of the project including publications. In the two first quarters of 2020 the team has begun to analyze the data of the 25,000 samples. Results are expected in Q1 2021.In terms of next steps, all data analysis results will be sent to the National Center for Health Statistics (NCHS) who then prepares a datafile by attaching clinical data and generating the study results, with a 90-day quality control review by JHU. The reviewed study file will ultimately be returned to NCHS for posting on the NHANES public-use website, which is one of the key deliverables of this project. These results will be used to generate publications. The NHANES will publicly make available a dataset from data generated from the JHU labs via the NCHS website to investigators across the globe on the distributions (including reference ranges in young, healthy persons) and determinants of these novel biomarkers in a nationally representative sample of the U.S. population.	$1,325,000	May-13

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Dean R O'Neill Renal Cell Cancer Research Fund	This memorial is in honor of Mr. Dean O'Neill, who, before he passed away, was treated for renal cancer by Richard Childs at NHLBI. FNIH is working with the O'Neill family to raise additional funds to support a post doctoral fellow to work in Dr. Richard Childs' lab, focusing on renal cell cancer research. The goal of this program is to provide critical person-power to accelerate the search for new breakthroughs in the treatment of kidney cancer. With significant contributions from individual donors and the BOO! Run For Life 10K, these funds sponsor a dedicated fellowship program to support the exploration of new and existing treatments, such as allogeneic stem cell transplantation, chemotherapy, radiation therapy, immunotherapy, vaccine therapy, and drug treatments. This program is managed by NHLBI with the support of FNIH.	FNIH staff continued to work with Brian O'Neill for this year's Boo Run. The event transitioned to a virtual social media-led campaign. A report was submitted from O'Neill/Rancic Fellow Dr. Stefan Barisic to O'Neill Fund supporters.	$684,648	Dec-03
Dr. Edward T Rancic Memorial Fund for Cancer Research	The Dr. Edward T. Rancic Memorial Fund supports a post-doctoral fellowship in Dr. Richard Childs' lab that focuses on renal cell cancer research. The fellowship was established by the family in memory of Dr. Edward Rancic.	FNIH continued to make outreach attempts to Bill Rancic. A stewardship report was received from the O'Neill/Rancic Fellow Dr. Stefan Barisic.	$156,475	Jul-04

NATIONAL
INSTITUTE
ON AGING

National Institute on Aging

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Alzheimer's Disease	In early 2014 a final research plan for AD was completed through AMP-AD Steering Committees, including representatives from AbbVie, Sanofi, Biogen Idec, GlaxoSmithKline, and Lilly as well as members from government and advocacy sectors. The AMP AD effort comprises two projects: Project A will supplement the biomarker panels already included in three NIH-funded Phase II/III registration trials in presymptomatic AD through the addition of tau PET imaging and novel fluid biomarkers. Project B will apply integrated network analysis (both RNA and proteomic studies) in human AD brain samples to identify biologic nodes and and networks linked to the development or progression of AD and create standardized open-source data structures and formats for easy analysis of biological data.	Overall, there has been continued progress in both Project A and Project B of AMP-AD over the past 5 years – milestones have been met and some have been expanded thanks to additional NIA funding. For Project A: Enrollment complete and open label extension initiated. Pre-random ization data for participants continue to be available via LONI. For Dian Trial, the trial has been completed and results communicated. A4 Study has randomized 1168 participants. Tau scanning has proceeded as planned. We now have 394 baseline tau PET scans, in addition to 344 visit 27 scans, 194 visit 48 scans, 56 visit 66 scans, and 5 early terminations scans for a total of 993 scans. Additionally, Project B related biomarker pilots have concluded with all relevant data released via the updated AD-Knowledge Portal. The FNIH continues to collaborate with the NIA on the close-out of AMP AD 1.0 to enable a transition into a potential second phase of the project.	$24,263,000	Oct-12
Accelerating Medicines Partnership - Alzheimer's Disease 2.0	The goal of the second phase of this transformative partnership is to expand the open-science, pre-competitive enterprise and facilitate a true precision medicine approach to target and biomarker discovery. This will be achieved by utilizing established knowledge, collaborations, tools, and resources to expand existing data generation pipelines to include diverse cohorts and longitudinal data enabling the partnership to refine target prediction and capture biomarkers. This partnership will leverage NIA's $64.5 million investment in the following strategic directions: Expand the molecular profiling in samples from diverse cohorts / Generate longitudinal metabolomic and immunologic profiling data to enable dynamic modeling of the disease trajectory / Expand the existing single-cell molecular profiling efforts to develop a single-cell molecular atlas of AD	The Foundation for the National Institutes of Health (FNIH) and the National Institute on Aging (NIA), a part of the National Institutes of Health (NIH) have a new, second Accelerating Medicines Partnership (AMP) initiative in Alzheimer's Disease (AMP AD 2.0). The AMP-AD 2.0 development effort builds on the AMP-AD 1.0 The goal of the second phase of this transforma tive partnership is to expand the open-science, precompeti tive enterprise and facilitate a true precision medicine approach to target and biomarker discovery. AMP AD 2.0 will considerably enhance and further transform Alzheimer's research by: (1) The Identifying and validating; (2) Increasing access to data from racially and ethnically diverse cohorts; (3) Expanding and refining understanding of disease pathways; (4) Enhancing data-sharing capabilities. The fundraising was ongoing through Q4 of 2020 and successfully completed January 2021. The official launch of AMP AD 2.0 is planned for Q1 2021 with a press release, launch event, establishment of the steering committee, and initiation of relevant contracting processess.	$10,760,000	TBD
Alzheimer's Disease Neuroimaging Initiative - Amyloid PET Early Frames Add on Study	The project is an add on study to the Alzheimer's Disease Neuroimaging Initiative (ADNI) third phase.The overall goal is to obtain a PET measure reflecting cerebral blood flow in ADNI participants by collecting amyloid PET data immediately after injection of an amyloid tracer.The project proposes to use up to 200 ADNI subjects distributed across the diagnoses of normal, mild cognitive impairment, and Alzheimer's Disease.The observations from this Project have two potential uses in clinical studies. One is that acquisition of early frame data can be used to derive a "functional" measure of cerebral blood flow that may change differently over time and may reflect effects of treatment that differ from measures of amyloid accumulation.Second, the measures of tissue perfusion can potentially be used to "correct" the amyloid deposition images obtained at later time points, in order to remove the effects of perfusion changes over time that might particularly affect longitudinal measurements.	The overall goal of this ADNI3 amyloid PET add-on study is to obtain a PET measure reflecting cerebral blood flow in ADNI participants by collecting amyloid PET data for 20 min immediately after injection of the amyloid tracer. ADNI Early Frames progress as of end of September has 56 participants pass initial screening. Currently there and over 54 individuals that have been enrolled and scanned in the Early Frames study. COVID-19 has had a substantial impact on ADNI3 and Early Frames visits. The enrollment numbers are lower than the projected 100 at the time of our last report. The COVID-19 pandemic impacted enrollment for Year 2 reporting, but we do anticipate achieving the targeted 100 subjects. There are sites that have been able to continue enrolling. In Q4 it was reported that there were 23 sites approved with 8 actively enrolling. Dr. Suzanne Baker (UC Berkeley) presented to the ADNI PPSB PET Endpoints working group on the correlations between FDG and 1. early AV45, 2. R1 derived from SRTM and SRTM2 using ADNI2 Early Frames data.	$825,000	Jan-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Alzheimer's Disease Neuroimaging Initiative 3	ADNI 3 is the extension of the ADNI study for an additional five years (August 1, 2016 - July 31, 2021). ADNI tracks volunteers at 60 clinical sites in the United States and Canada with normal cognition, mild cognitive impairment and Alzheimer's disease to create a widely-available database of imaging, biochemical and genetic data. Additions to ADNI 3 include recruiting 1,200 volunteers to join about 800 current participants to enrich the existing dataset, tau PET imaging, and cutting edge systems biology analyses. ADNI 3 also will assess cognitive function through computer tests at home and in the doctor's office and measure changes in subjects ability to handle money, which can be a warning sign of the disease.	Program activities for ADNI 3 have continued, including monthly ADNI 3 PPSB Teleconfer ences, Biofluid Biomarker Working Group, Clinical Endpoints Working Group, and PET Endpoints Working Group activities. ADNI 3 continues to focus on patient recruitment – particularly for MCI, AD, and minority enrollment. As of December 2020, 987 Participant were enrolled of these 441 were rollovers from ADNI2 and 546 were new participants with a 142 representing minority participants. Currently enrollement is slowed due to COID-19 pandemic. There are 24 sites open at and able to conduct ADNI3 visits at full capacity, 15 open and able to conduct ADNI3 visits at partial capacity, 15 open but unable to conduct in-person visits for ADNI3, and 2 closed/unable to conduct any in-person research. Through Q4 2020 the ADNI 3 PPSB continued to their review to evaluate relevant updates in the feild as it pertains to Clinical Endpoints, Biofluid Biomarkers, and PET Endpoints. The Clinical Endpoints Working Group has reviewed 15 technologies to date and have presentations planned for a further 4 so far. The Biofluid Biomarkers Working Group have identified plasma and CSF biomarkers of interest to the PPSB and invited vendors that provide said biomarkers to present. Currently 7 have accepts. FNIH conducted a Fall ADNI 3 PPSB meeting virtual meeting with ADNI Core PI's and members invited to share updates.	$15,122,402	Aug-15
Biomarkers Consortium - Inflammatory Markers for Early Detection and Subtyping of Neurodegenerative Disorders	There is an acute need for biomarkers for diagnosing and subtyping patients with neurodegenerative disease and psychiatric disorders. CSF and plasma measurements of inflammatory markers represent an easily accessible biomarker opportunity with great potential, but require a harmonized, well-designed approach for sample collection, handling, and evaluation. While aberrant levels of inflammatory markers have been observed in patients, meta analyses of published studies show small effect sizes and large confidence intervals due to small sample size and the absence of a uniform analyte panel. Using technically well-validated, highly sensitive assays that operate in the linear range for biomarker quantification, and appropriately powered and harmonized sample collection and handling procedures, this 4-year Biomarkers Consortium project is expected to identify and validate plasma- and/or CSF-based multi-marker inflammatory biosignatures in Alzheimer's Disease and Major Depressive Disorder.	The Project Team will soon move forward with analyzing the Aim 1 sample set. All Aim 1 negotiation and agreements are in place except for NYU. The Project is considering backup sample sources as a sample agreement remains held up at NYU. The project team has received additional funding from partners for Aim 2 and begun preparations for Aim 2 testing. Planning continues for Aim 2 testing, including contract negotiations with an additional testing CRO and sample-contributing research centers.	$1,657,205	Dec-16
Biomarkers Consortium-SV2A PET Tracer as a Biomarker for Synaptic Density	Synapse loss is commonly thought of as an optimal biomarker for brain integrity and cognitive function as it correlates well with cognitive decline in AD and applies to all clinical trials regardless of a drug's mechanism of action. A crucial knowledge gap in the justification of the use of SV2A PET as a biomarker for disease progression and clinical trial response is the lack of understanding of the biological underpinnings of the change in PET signal. It is assumed (and highly likely) that a lower SV2A signal reflects a loss of synapses, but this has not been formally confirmed. Utilizing ground-breaking post-mortem immuno-electron microscopy methods and highly sensitive immunoassay characterization, this project will validate analytical performance of the SV2A [18F]SynVesT-1 as a monitoring or pharmacodynamic biomarker of synaptic density as a proof-of-concept in AD; accelerating the evaluation of novel therapeutics in neurodegenerative diseases.	The BC Executive Committee approved the Project Plan on September 11th, 2020. The SV2A PET Project Development Team (PDT) is currently making preparations for the project and have met to discuss the collaboration for collecting in vivo PET imaging. Fundraising is underway with two organizations joining as funding partners: AbbVie and BrightFocus Foundation. FNIH will start drafting project service and collaboration agreements during Q1 2021.	$1,166,729	TBD

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Plasma Aβ as a predictor of amyloid positivity in Alzheimer's disease	The objective of the current proposal is to apply the next generation of plasma amyloid beta assays to determine whether low plasma Abeta42/Abeta40 ratios increase the probability of identifying patients with amyloid positivity. Such a test could significantly improve clinical trial screening efficiency and reduce clinical trial costs for early Alzheimer's Disease. Additionally, this would decrease patient burden by limiting the number of lumbar punctures and PET scans needed for trial enrollment. This study aims to independently validate recently published findings by performing a head-to-head comparison of the most promising Abeta plasma measurement techniques in well characterized sample sets with comprehensive clinical data along with Amyloid PET and/or CSF data available for confirmation and analysis.	Study 1, Aim 2 of the project is in progress to test the performance of selected mass spectrometry (MALDI-TOF, LC/MS) or immunoassays assays to differentiate between Aβ-positive and -negative subjects. The assay vendors have received all samples necessary to perform the analyses starting in 2021. The Statistical Analysis Team refined the Statistical Analysis Plan and wrote the primary analysis code. When the Study 1 analysis is completed the project will be able to meet its next milestone, selection of assays for validation in Study 2 (platform comparison on clinical utility). The Project Team continues to plan for Study 2 which included a decision to use ADNI samples and is also further considering and refining a p-tau addendum to the Plasma Aβ project.	$2,403,433	Apr-19
Mechanisms of Cognitive Remediation in Older Adults	The vast majority of older adults experience some deterioration in cognitive function as they age. This initiative supports an intervention trial to remediate or prevent age-related cognitive decline. A key goal is to encourage therapeutic approaches that aim to drive beneficial plasticity of the aging brain and require investigators to monitor plastic changes through behavioral and biological markers. The McKnight Brain Research Foundation (MBRF) is the private funder/partner and committed $5 million to this effort. NIA's investment brings the total project funding to $15M.	FNIH entered into a Memorandum of Understanding (MOU) with NIA for this project in August 2013 and finalized its Letter of Agreement with the McKnight Brain Research Foundation (MBRF) in October 2013. NIA made a five-year grant award of $15M in late 2014 to fund a multicenter clinical research trial in cognitive aging: "Remediating Age Related Cognitive Decline: Mindfulness-Based Stress Reduction and Exercise." The Principal Investigator is Eric J. Lenze, MD, of the Washington University School of Medicine. NIA awarded a no-cost extension to the investigators through 2019. A final report is expected soon.	$5,000,000	Jan-08
Research Partnership in Cognitive Aging 3	With joint support from the McKnight Brain Research Foundation and the National Institute on Aging, this initiative will funds a new 5-year program in cognitive aging research, overseen by the NIA. It is expected that an RFA will be released in 2019.	The FNIH and MBRF entered into a 5-year, $5M commitment to support this program in 2018. NIA released the FOA in February 2020 and Advisory Council review is scheduled for May 2021, and awards are expected thereafter. The FNIH and the NIA have entered into a formal MOU to govern this project.	$5,000,000	Nov-20
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Developing Evidence-Based Music Therapies	Music-based interventions show significant promise for treating symptoms of devastating disorders of aging such as stroke, Parkinson's disease (PD), Alzheimer's disease (AD), and Alzheimer's disease related dementias (ADRD), as well as for improving function during normal aging. A major limitation to more widespread application of music interventions in aging populations is the scarcity of data from rigorous, well-powered randomized controlled clinical trials. Harnessing the therapeutic potential of music is of wide interest across the National Institutes of Health (NIH). The proposed project aims to create a research roadmap for establishing more effective music-based interventions (MBI) to combat disease and increase quality of life for millions of individuals suffering from neurological disorders and other conditions of aging.	The FNIH POC approved involvement in this project with a focus on securing funding for Phase 1: Development of the NIH Toolkit. The FNIH submitted a proposal to the Renee Fleming Foundation for partial support of Phase 1 in October 2020; the proposal was funded in January 2021.	$61,850	TBD

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers	The National Institute on Aging is hosting its second National Research Summit on Dementia Care: Building Evidence for Services and Supports, to be held on March 24-25, 2020 in Bethesda, Maryland. The Summit will build on the foundation laid by the 2017 National Research Summit on Dementia Care. Through the Summit, the National Institute on Aging seeks to accelerate the development, evaluation, translation, implementation and scaling up of evidence-based and evidence-informed services for individuals with dementia, their family and caregivers. The Summit will bring together experts in research on care, services and supports in order to develop recommendations for research that will inform annual updates to the National Plan to Address Alzheimer's Disease and advance both public sector and private sector delivery of services.	The event was rescheduled due to COVID-19 and became three remote sessions--the name was updated to "Summit Virtual Series: 2020 National Research Summit on Care, Services, Supports for Persons with Dementia and Their Caregivers." The remote events were held on July 10, July 21 and August 13. Sponsorships were secured from the Alzheimer's Association, The Association for Frontotemporal Degeneration, Avanir Pharmaceut icals, Biogen, Home Instead Senior Care, and The Shiley Foundation. Donors were pleased with the virtual format and efforts around the event have concluded. This project is now closed.	$60,000	TBD

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

National Institute of Allergy and Infectious Diseases

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Developing Endpoints for Clinical Trials in CABP and Skin Infections	The goal of this project is to develop approaches that will help the FDA develop efficacy outcome measures (endpoints) for modern-day clinical trials of investigational agents for community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) that can be tied to historical data in each indication, thereby providing the basis for sound non-inferiority (NI) trial design and NI margin justification. A key deliverable includes the development and content validity of a Patient-Reported Outcome (PRO) instrument for CABP and ABSSSI to use as a tool to assess how a patient feels, functions and survives in anti-infective clinical trials and studies. The project launched in January 2012.	Both the CABP (Pneumo-PRO) and ABSSSI (SKINFECT- PRO) patient reported outcome (PRO) instruments are complete, copyrighted, and FNIH has established a licensing agreement with the MAPI Research Trust to distribute and manage the use of these clinical tools to the field (https://e provide.map i-trust.org /instrument s/community -aBoth the CABP (Pneumo-PRO) and ABSSSI (SKINFECT- PRO) patient reported outcome (PRO) instruments are complete, copyrighted, and FNIH has established a licensing agreement with the MAPI Research Trust to distribute and manage the use of these clinical tools to the field (https://e provide.map i-trust.org /instrument s/community -acquired-b acterial-pn eumonia-sym ptom-diary). ICON received a FDA BAA award to support the psychometric validation of the PROs, however with challenges in patient enrollment and inclusion criteria, the FDA has ended its contract with ICON due to slow recruitment. ICON and the FNIH have closed out the contracts for the project.cquired-b acterial-pn eumonia-sym ptom-diary). ICON received a FDA BAA award to support the psychometric validation of the PROs, however with challenges in patient enrollment and inclusion criteria, the FDA has ended its contract with ICON due to slow recruitment. ICON and the FNIH have closed out the contracts for the project and the project is expected to close in Q4 2020.	$820,000	Jan-11
Biomarkers Consortium - HABP/VABP Working Group	The goal of this project is to 1) develop reliable, well-defined, clinically relevant endpoints for Hospital-Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP) and 2) develop at patient reported outcome that measure tangible benefits for patients in terms of how they feel, function and survive. Currently, there are limitations in the information to quantitatively assess the effect of antibacterial drug treatments vs. no treatment or placebo and in comparisons between active agents. These undefined clinical endpoints impede the field of drug development for these indications and limit the ability to perform clinical trials in this area. The lack of outcome measures impedes patient care since clinicians and patients cannot understand similarities and differences between therapeutic agents that are not measured in a well-defined, reproducible and clinically relevant manner.	The HABP-VABP Project completed its primary aims with the FDA docket submission to provision strategies for HABP and VABP clinical trial design and provide an update to the symptomatic endpoints for these disease indications. The submission occurred on June 5, 2017 and the results of the project were presented at ECCMID in April of 2018 and now published in January 2019 in the Journal of Infectious Disease (JID). The manuscript was in the top 10 downloaded articles in the last two years for JID. The FNIH Project Team also had developed a draft HABP PRO instrument and completed content validity in partnership with ICON plc. The HABP PRO content validity established that patient responses of how they feel, function, and survive were very strongly aligned with CABP and therefore the Pnemuo-PRO tool would also support HABP populations. The project is closed as of Q4 2020.	$361,500	May-13

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine	The proposal objectives are to identify epitopes for broadly effective antiodies against influenza A and B that are most suitable for vaccine elicitation. Employ antigenically-assessed structural mimics (created in multivalent formats) to elicit antibodies capable of neutralizing diverse influenza viruses. And lastly, optimize iteratively target antibody responses to achieve titers in animals that protect from diverse influenza virus challenge.	The FNIH is working to amend the MOU with NIAID and the sub-award agreement with Columbia University to reallocate structural imaging efforts which can be done more efficiently at Columbia using CryoEM. Budgeted funding will be reallocated to fall in line with the proposed changes to the project plan. The first annual report was submitted in September 2020 and they look forward to a successful second year with minimal lab restrictions and continued uninterrupted efforts, amidst the COVID-19 pandemic.	$1,750,000	Aug-19
Comprehensive Cellular Vaccine Immune Monitoring Consortium	The goal of this program is to provide high-quality cellular immune monitoring to the Collaboration for AIDS Vaccine Development (CAVD), a consortium of consortia funded by the BMGF to discover, test and develop candidate vaccine strategies to prevent the transmission of HIV. The Comprehensive Cellular Immune Monitoring Consortium (CCVIMC) provides a coordinated effort for assessing vaccine-elicited T and B cell responses in humans and nonhuman primates that facilitates the sharing of standardized data sets and allows for data mining capabilities. In the current iteration of the program (third 5-year grant), both T and B cellular immune monitoring assays are being improved and new tools are being developed through the application of cutting-edge technologies. In addition to taking the lead role in administrative oversight of the entire operation, the Foundation for the NIH provides scientific project management support to lead scientific director and consortium PI, Richard Koup (VRC/NIAID).	The CCVIMC is nearing the end of its current 5-year awards. In the next couple months, the FNIH will submit a proposal for a new award with the BMGF which is anticipated to start in July 2021. Dates for the 2021 CA/CCVIMC SAB Annual Meeting have been selected, May 20-21, 2021, to be hosted on a virtual platform	$17,444,918	Jul-16

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Developing leads to shorten duration of TB chemotherapy: SHORTEN-TB	SHORTEN-TB will build upon the lessons learned from HIT-TB and from other recent advances in our understanding of the rate-determining lesions in determining the treatment shortening potential of individual TB drug series as early as possible. We will progress advanced series from the HIT-TB program that are predicted to be associated with those characteristics that define agents with potential to shorten the duration of chemotherapy based on clinical evidence (oxazolidinones) or mechanistic novelty where the engaged targets are predicted to be essential in the context of human pathogenesis.	In November 2016, FNIH was awarded a grant from the Bill & Melinda Gates Foundation to manage the SHORTEN-TB project. In addition to the NIAID, the sub-awardee partners are based in the UK, Germany, and South Africa. The group ratified a Research Collaboration Agreement in May 2017. The project held annual team meetings of the collaborating partners in Cape Town, South Africa and in Saarbrücken Germany. The year 3 annual progress report was submitted in February 2020 to the donor. The grant was approved for a no-cost extension to January 31, 2021.	$7,575,351	Nov-16
Global Health Fund	FNIH has many programs at work in dozens of countries around the world as well as across the United States. The programs aim to alleviate wide spread suffering and death from diseases such as malaria, enteric infections and HIV, as well as train researchers and medical personnel in the developing world. The Global Health Fund was established by FNIH in January 2013. Contributions directed to this fund will be used within the global health field as directed by FNIH.	No recent activity.	$4,495	Jan-13
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines	The primary outcome that this investment will achieve or significantly contribute to is the development of a protective HIV vaccine, which is believed to be the only means to end the HIV/AIDS pandemic at the global level. The scope of this work is to evaluate innovative mRNA-based vaccines encoding full-length membrane-anchored trimeric HIV-1 envelopes (Envs) presented on Gag/Gag-protease virus-like particles (VLPs). The study will employ an original approach based on a mixed model (both lineage-based and structure-based). It will employ HIV-1 Envs that naturally engage germline Abs at the start, and then add two consecutive steps: initially, boosts with fully closed autologous Env (tier-2, no glycan holes) and then mixed heterologous tier-2 Envs from two different clades. The approach seeks to expand and affinity mature B-cell lineages against shared epitopes, i.e., bNAbs. Preliminary results obtained with this approach in a first small-scale study showed the development of robust autologous and low-level broadly neutralizing responses against a global panel of tier-2 HIV-1 pseudovirions. Limited EM analysis showed VRC01 and PG16-like Ab reactivity. In addition, partial protection from a highly virulent heterologous SHIVAD8 intrarectal low dose virus challenge was seen in 7 macaques from two groups of 4 that received this type of vaccine given by either mRNA/LNP alone or mRNA/LNP + protein and was correlated with serum Abs to the CD4bs and ADCC against cells expressing the closed AD8 Env trimer. The goal of the current grant would be to confirm and extend these promising initial results in a statistically well-powered vaccine-challenge study in rhesus macaques and to define an optimized vaccine formulation and administration schedule for the transition toward clinical studies.	Amendments to the MOU with NIAID and sub-award agreement with Columbia University have been finalized to reallocate funds associated with the structural imaging efforts. Amidst COVID-19 pandemic delays, we will be requesting an NCE from the funders.	$1,460,000	Nov-20

Research	C	C		
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Onchocerca volvulus-specific biomarkers for macrofilaricidal activity	The study will employ an original approach based on a mixed model (both lineage-based and structure-based). It will employ HIV-1 Envs that naturally engage germline Abs at the start, and then add two consecutive steps: initially, boosts with fully closed autologous Env (tier-2, no glycan holes) and then mixed heterologous tier-2 Envs from two different clades. The approach seeks to expand and affinity mature B-cell lineages against shared epitopes, i.e., bNAbs. Preliminary results obtained with this approach in a first small-scale study showed the development of robust autologous and low-level broadly neutralizing responses against a global panel of tier-2 HIV-1 pseudovirions. Limited EM analysis showed VRC01 and PG16-like Ab reactivity. In addition, partial protection from a highly virulent heterologous SHIVAD8 intrarectal low dose virus challenge was seen in 7 macaques from two groups of 4 that received this type of vaccine given by either mRNA/LNP alone or mRNA/LNP + protein and was correlated with serum Abs to the CD4bs and ADCC against cells expressing the closed AD8 Env trimer. The goal of the current grant would be to confirm and extend these promising initial results in a statistically well-powered vaccine-challenge study in rhesus macaques and to define an optimized vaccine formulation and administration schedule for the transition toward clinical studies.	The FNIH was awarded a grant from the Bill & Melinda Gates Foundation in August 2018. The project supports two partner institutions through sub-award agreements with the NIAID and New York Blood Center. The first year annual report was submitted in February 2020 to the Gates Foundation. The grant was awarded a no-cost extension through December 2020.	$340,616	Aug-18
Structure-based Vaccine Design Against HIV-1	fNIH has many programs at work in dozens of countries around the world as well as across the United States. The programs aim to alleviate wide spread suffering and death from diseases such as malaria, enteric infections and HIV, as well as train researche	The program PIs have requested a 6-month NCE due to delays resulting from the response to the COVID-19 pandemic. In addition, a funding supplement is being considered pending progress that will be reported in the next quarterly status update.	$602,859	Mar-17
Understanding NHP protection against TB induced by intravenous BCG	Two billion people worldwide are infected with Mycobacterium tuberculosis (Mtb) resulting in 10 million cases of clinical disease and 1.5 million deaths each year. The hurdles for developing a highly protective and durable vaccine against Mtb require addressing four central tenets of T cell immunology – magnitude, quality, breadth, and location of the response. These specific elements of the problem will be addressed by focusing on how changing the dose and route of administration from intradermal (ID) to intravenous (IV) greatly increases the vaccine's ability to protect rhesus macaques from infection following exposure to Mycobacterium tuberculosis (Mtb), the bacterium that causes TB.	The FNIH executed a grant amendment with the Bill & Melinda Gates Foundation for additional studies under this grant. The project end date was extended through December 1, 2022.	$6,313,721	Jul-18

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Using Biomarkers to Predict TB Treatment Duration	This is a prospective, randomized, noninferiority phase 2b clinical trial of pulmonary drug sensitive TB subjects in South Africa and in China. PredictTB makes use of state-of-the-art tools (specifically, PET/CT imaging and GeneXpert) to identify participants with a lower burden of disease , and will test whether treatment can be shortened to 16 weeks in this lower risk cohort. The study hypothesizes that a combination of microbiological and radiographic biomarkers will identify patients with tuberculosis who are cured with 4 months (16 weeks) of standard treatment.	The NIAID Data and Saftey Monitoring Board (DSMB) met on September 11, 2020 to review data and a recent efficacy analysis for the PredictTB Trial. The board recommended halting the randomization to study arms B and C, and continuing patient follow-up per the protocol.	$12,932,525	Nov-16
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
African Centers of Excellence - Uganda	The National Institute of Allergy and Infectious Diseases will establish a bioinformatic center, the African Centers for Excellence, in Kampala, Uganda. The program will create a tele-learning center at Makerere University that provides high-performance scientific computing infrastructure, a "Collaboratory" space for consultations and a virtual reality-based laboratory, for students studying to receive a graduate degree in bioinformatics.	Letters of Agreements have been executed with the following partners: Makerere University, Enduvo, BioTeam, Texas Advanced Computing Center, and Research Education and Network for Uganda (RENU). The process of finalizing and executing the NIAID-FNIH ACE-Uganda Memorandum of Understanding is underway.	$86,500	Feb-19
Pew Latin American Fellows in the Biomedical Sciences Program	The Pew Latin American Fellows in the Biomedical Sciences program has awarded a Pew Latin American Fellows award to support the research of several post-doctoral fellows within a laboratory at an NIH institute. The Pew Charitable Trusts asked to use the FNIH as a conduit to provide awards to the Fellows.	FNIH currently manages four Pew Latin American Fellow awards: 1) Dr. Vinicius de Andrade-Oliveria, NIAID, who has returned to Brazil to establish his own lab. 2) Dr. Djalma de Souza Lima Junior, NIAID, 3) Dr. Diego Fernandez, NIMH, who has received an one-year no-cost extension through 2020, and, 4) Dr. Eunice Dominguez Martin, NINDS, who is the latest grant recipient as of August 2020.	$708,750	Aug-09
Roth Fellowship for CAEBV-HV Research	Richard and Susan Roth are donating to fund a 2 year Fellowship in the lab of Dr. Jeffrey Cohen of NIAID. The Fellow will conduct research to accelerate efforts to find new drugs to treat Chronic Active Epstein Barr Virus (CAEBV) and Chronic Active Epstein Barr Virus-Hydroa Vacciniforme (HV) as well as find and understand genetic causes of the diseases to lead to new treatments. Richard and Susan Roth's grandson, Aiden Aronoff, suffers from CAEBV-HV.	Mr. Roth reaffirmed his commitment to support Dr. Cohen's research on CA-EBV/HV research.	$105,200	Feb-14
Swanson Family Fellowship in Genetic Thyroid Benign Chorea & IgA Deficiency (TTF-1)	The Swanson Family Fellowship supports research in TTF-1 Mutation Causing Benign Chorea in the laboratory of infectious diseases under the direction of Steven M. Holland, M.D., Chief of the Laboratory of Clinical Infectious Diseases at the National Institute of Allergy and Infectious Diseases at NIH.	Dr. Steven Holland of NIAID provided an update of needs in his laboratory that might be supported by the Fund. FNIH sent the donors a proposal for use of the funds, but has received no response from the outreach efforts. FNIH Advancement staff continue periodic outreach efforts to the Swanson Family regarding their gift, but have had no response.	$92,500	Oct-06

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
The Dr. Franklin A. Neva Memorial Fund	This Fund supports two ongoing programs to honor the memory and further the legacy of Dr. Franklin A. Neva, a former director of NIAID's Laboratory of Parasitic Diseases (LPD). The first is an annual lecture on a topic related to clinical tropical medicine and associated pathophysiology as part of the LPD's ongoing weekly lecture series. The second is an annual session devoted to parasitic and/or tropical medicine that features discussions of individual cases held by the LPD and the Greater Washington Infectious Disease Society.	FNIH staff confirmed the schedule for GWIDS lectures and rescheduled Neva Lecture to be held virtually in 2021.	$51,059	May-12

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
AMP Autoimmune and Immune-Mediated Diseases (AMP-AIM)	The AMP Autoimmune and Immune Mediated Diseases (AMP AIM) aims to accelerate the discovery of new mechanisms of autoimmune diseases and new targets for intervention and therapeutic development. The cornerstone of AMP AIM will be the concept of disease reconstruction based on high dimensional study of cell interactions. The program will not only refine and extend the single cell analysis of tissue to other autoimmune diseases (disease deconstruction), but will also bring in high dimensional novel analytics to discover how innate and adaptive cells of the immune system and tissue resident cells network with each other to cause inflammation, injury, abnormal function and clinical disease (disease reconstruction). AMP AIM will focus on: 1) dissecting mechanisms of disease at the organ level in RA, lupus, Sjogren's and Psoriatic Disease Spectrum, leveraging current resources and infrastructure; 2) spatially map cell types and states to identify the pathways of crosstalk between cells that drive inflammation and damage; and 3) establish a comprehensive knowledge and data portal for broad and accelerated data sharing to the inflammation and autoimmunity field.	During Q4 2020, the AMP AIM program has been focused on solidifying financial commitments of support from multiple NIH Institutes and working with NIH and private sector leadership to drafting the research plan. NIH has committed to $26.5M from 3 institutes (NIAMS, NIAID, and NIDCR) and the Office of Research on Woman's Health (ORWH). A draft plan is being circulated and finalized and will be shared with all potential partners in February. FNIH will be targeting a minimum of 10 companies (7 from the existing RA/SLE program) to support the $63M plan. Pharmaceut ical partner letters of agreement of $750K per year for 5 years ($3.75M) will be secured by the end of Q2 with a plan to launch the program in October of 2021. The new cornerstone of AMP AIM will be the concept of disease reconstruc tion based on high dimensional study of cell interactions. AMP AIM will not only refine and extend the single cell analysis of tissue to other autoimmune diseases (psoriasis, psoriatic arthritis and sjogren's syndrome) but will also bring in high dimensional novel analytics to discover how innate and adaptive cells of the immune system and tissue resident cells network with each other to cause inflammation, injury, abnormal function and clinical disease. A buy-up proposal to include additional autoimmune and immune mediated diseases (atopic dermatitis, scleroderma, ankylosing spondylitis, others) will be incorporated into the plan which may enable even greater investment by private and public partners.	$500,000	TBD
Accelerating Medicines Partnership: Rheumatoid Arthritis, Systematic Lupus Erythematosus & Related Autoimmune Disorders	The Accelerating Medicines Partnership (AMP), is a pre-competitive effort among government, academia and industry to harness collective capabilities, scale and resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases – Type 2 Diabetes, Alzheimer's Disease, and Rheumatoid Arthritis, Lupus and Related Autoimmune Disorders. In Dec 2013 a final research plan for RA-Lupus was completed through the RA-Lupus Steering Committees, including representatives from AbbVie, BMS, Janssen, Merck, Pfizer, Sanofi, Takeda, multiple key disease-focused not-for-profits and government. The plan focuses on the molecular analyses of gene expression and signaling in specific subsets of leukocytes and resident cells in control and RA synovium and blood and Lupus kidney biopsy, skin and blood. This may lead to biomarkers which predict pathological processes that lead to end-organ damage and identify potential new pathways or target for drug development and intervention.	The AMP RA/Lupus Program continues Phase 2 analysis of both the RA and SLE pipeline studies including single-cell RNA-seq expression profiles in kidney, synovium, blood and urine samples. Due to the COVID pandemic, NIH grant support was extended through the end of May 2021. FNIH research collaborative agreement with Johns Hopkins University (JHU, urine proteomics) and Brigham and Woman's Hospital (tissue and blood CyTOF) were extended to the end of Q3 2021. An additional statement of work is being funding for SLE histology immunofluo rescence at JHU. An upcoming RA data webinar is planned for the week of April 19 and a SLE-specific data webinar will follow most likely in late May. Several prominent presentations on program data were part of an AMP RA/SLE symposia at the recent ACR Convergence meeting in Q4 2020. Links to these presentations and associated manuscripts can be found on the current FNIH webpage: https://www.fnih.org/our-programs/AMP/amp-ra-sle	$27,800,557	Mar-14

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Biomarkers of Diagnosis and Disease Activity in Axial Spondyloarthritis	Axial spondyloarthritis (axSpA) is a highly morbid chronic debilitating condition presenting with chronic inflammatory low back pain and stiffness caused by inflammation of the sacroiliac joints and lumbar spine. No serologic tests are available to aid in the diagnosis, existing biomarkers are neither sensitive nor specific, and plain radiographs are often negative early in disease. This has resulted in delays in diagnosis of up to 10 years for patients and have caused the FDA to reject multiple applications for new therapies based on concerns about reliable diagnosis or accuracy in monitoring disease activity and treatment response. The project plans to utilize proteomics and whole-blood RNA expression profiling to both validate and expand on existing biomarkers and pathologic pathways for axSpA diagnosis and disease monitoring. The study will utilize on the infrastructure, established data and patient samples from two ongoing patient studies: Prospective Study of Outcomes in Ankylosing Spondylitis (PSOAS) and Classification of axSpA Inception Cohort (CLASSIC)/SPARTAN registry.	The overall goals of the axial spondyloar thritis (axSpA) project are to utilize high-throu ghput proteomics, genome-wide association studies (GWAS) and whole-blood RNA expression profiling to: discover protein and RNA expression biomarkers for diagnosis of non-radiog raphic (nr)-axSpA and axSpA compared to lower back pain controls, and develop susceptibi lity biomarkers that measure the risk of axSpA disease. The study will utilize the infrastruc ture, established data and patient samples from two ongoing patient studies: Prospective Study of Outcomes in Ankylosing Spondylitis (PSOAS) and Classifica tion of axSpA Inception Cohort (CLASSIC)/ SPARTAN registry. The primary focus of the plan will be on peripheral measures using serum proteomics (RayBio L2000 arrays). The project plan is scheduled to come before the BC Executive Committee for review in late Q1 2021.	Fundraising efforts are underway	Sep-19
Biomarkers Consortium - PROGRESS OA - Osteoarthritis (OA) Biomarkers Qualification	PROGRESS OA - Clinical Evaluation and Qualification of Osteoarthritis Biomarkers Project is the second phase of a two-stage strategy to address the most fundamental obstacles to the development of new treatments for Osteoarthritis (OA). This project will validate the highest performing radiographic measures, MRI measures and biochemical markers from the Phase I OA Biomarkers Consortium Project, which was completed in 2015. This project will combine data sets from six previously conducted clinical trials and will analyze whether the imaging and fluid biomarkers can predict OA disease progression. The ultimate goal is to qualify the biomarkers with the FDA and EMA to be used as a prognostic markers of OA disease progression for use in OA drug development. The results of PROGRESS OA Project will provide a set of qualified biomarker tools that will impact clinical trial design by decreasing the number of patients needed, and decreasing the time and costs needed for OA drug development.	The image analysis for PROGRESS OA has begun as of Q4 2020, this includes quantitative and semi-quant itative measures of knee MRIs and x-rays from placebo patients from multiple OA clinical trials. Coordination of these efforts are being orchestrated through the project CRO at BioClinica. Data Sharing Agreements (DSAs) have been finalized with Pfizer and AbbVie for additional images to be included in the project. A service contract with Nordic Biosciences to test the serum and urine biochemical biomarkers has been executed in Q4 2020 and the testing in currently ongoing. The Project Team is following up with FDA regarding the status of the MRI qualification plan submitted to FDA in January 2020. The preparation of the biochemical qualification plan will begin Q2 2021.	$2,732,000	Mar-16
Biomarkers Consortium - TARGET Biomarkers Study	Cardiovascular disease (CVD) is the leading cause of deaths in the general population, however Rhuematoid Arthritis (RA) is associated with an increased risk of developing CVD by almost two fold. Therapies that reduce joint inflammation in RA patients may also reduce CVD disease. This project seeks to utilize validated proteomic biomarkers of RA disease activity and inflammation to categorize baseline and DMARD-associated changes in vascular inflammation - measured by FDG PET-CT - in RA patients. Leveraging a NIH randomized controlled clinical trial (The TARGET Trial), this companion BMx project will compare and correlate the changes in these proteomic biomarkers with vascular FDG PET-CT between two treatment regimens in methotrexate inadequate responders that represent a critical and common decision point for rheumatologists and patients: addition of a TNF inhibitor vs. addition of sulfasalazine plus hydroxychloroquine (triple therapy) to background MTX.	The NIH TARGET clinical trial completed enrollment of the 150 patient recruitment goal in October 2020. The NIH trial randomized patients between two treatment regimens: either the addition of a TNF inhibitor or addition of sulfasalazine plus hydroxychl oroquine (triple therapy) to background MTX. The FNIH biomarker project seeks to utilize validated proteomic biomarkers of RA disease activity (VectraDA) and an exploratory protein panel (Myriad RBM) of inflammation and cardiovasc ular disease to categorize baseline and DMARD-asso ciated changes in vascular inflammation in RA patients. Biomarker testing is being provided in-kind from the providers and testing will start in mid-2021. Data and results of the TARGET Biomarker Study will be compared and correlated to the NIH TARGET Trial outcomes which are changes in vascular FDG PET-CT.	$1,275,000	Sep-14

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

National Institute of Biomedical Imaging and Bioengineering

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Remote Monitoring for Medical Product Development Workshop	As mobile monitoring health technologies (e.g. smartphone apps, wearables, and mobile-device-based tools) – hardware and software – become increasingly available to consumers, providers, and researchers, there are new opportunities to better connect patients and health care providers. Real-world data and measurements from these digital technologies could improve the patient experience and incorporate this patient input in support of novel biomarkers for use in drug research and development (R&D). This workshop will provide a venue to discuss challenges, and opportunities in mobile monitoring health technologies for improving the probability of success in drug development and enabling precision medicine and considerations for an evidence-based framework for applying mobile monitoring health technologies towards drug research and development.	Workshop participants identified a framework to guide the process of developing remote monitoring measures and prioritized a list of high-impact endpoints or measures that can be recorded through mobile sensing. The workshop planning team incorporated the insights from the meeting into multiple manuscripts and core recommendations to enable a framework for the analytical and clinical validation needed for drug developers and to develop and improve operational/ regulatory guidance. This project is closed. More information can be found at: https://fnih.org/our-programs/biomarkers-consortium/digitalmonitoring		Aug-19

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

National Institute of Child Health and Human Development

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
A plus Trial (NICHD / Global Network)	This study proposes to conduct a clinical trial to assess the value of a single oral dose of azithromycin to prevent maternal death or peripartum sepsis and intrapartum/neonatal death or sepsis in laboring women. The trial will be conducted through NICHD's Global Network for Women's and Children's Health Research, which supports and conducts clinical trials in resource-limited countries by pairing foreign and U.S. investigators, with the goal of evaluating low-cost, sustainable interventions to improve maternal and child health and build local research capacity and infrastructure. The project would evaluate the value of a single oral dose of azithromycin (plus usual care) in a population of approximately 34,000 women in labor across south Asia, sub-Saharan Africa, and Central America. This will involve a collaboration between NICHD and the Bill & Melinda Gates Foundation (BMGF). The FNIH would serve as the recipient of the BMGF award and would manage sub-awards to the Data Coordinating Center at RTI and US affiliates of the eight partner sites. The study will include a subset of 5,500 high risk women, at the highest risk for infection because they have prolonged labor (≥18 hours) and/or prolonged membrane rupture (≥8 hours), and 28,500 low-risk women. In addition, BMGF wishes to add biospecimen and antibiotic resistance measurements for the full sample. The low-risk cohort increases the generalizability of the study findings significantly, which increases the utility of the study in helping to inform sounder health care policy for women and children.	The FNIH was awarded a grant from the Bill & Melinda Gates Foundation in August 2019 to support the study. The project will support eight U.S. partner institutions and one Data Coordinating Center through sub-award agreements. A pilot study was conducted beginning in late 2019 and resumed through mid-2020 due to a pause caused by the COVID pandemic. The pilot enrollment was successful. Enrollment for the full study was begun in Q3 of 2020.	$6,687,509	Oct-19
Biomarkers Consortium - Preeclampsia	To qualify diagnostic and predictive aangiogenic, imaging and nucleic biomarkers to for early diagnosis and treatment of preeclampsia.	Concept was unanimously approved by the MDSC on Nov 18, 2020. The concept will be shared with the BC EC on March 1, 2021. FNIH is in discussions with pharmaceutical companies, assay developers, and other organizations to expand the project plan.	Fundraising efforts are underway	TBD

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

National Institute of Dental and Craniofacial Research

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Diagnostic Biomarkers of Sjögren's Syndrome	The Sjögren's Syndrome (SS) project will be managed by the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium, through the Inflammation & Immunity Steering Committee. The primary objective of this project is to develop and validate diagnostic biomarkers in SS patient subgroups by better defining and understanding disease heterogeneity and identifying diagnostic biomarkers for patient stratification. Multi-dimensional molecular characterization of disease spectrum in diverse SS and sicca populations will be performed, followed by tests for associations with clinical sub-phenotypes in salivary gland tissue. The project also aims to identify blood-based molecular signatures that correlate with salivary gland signatures and clinical sub-phenotypes for development of minimally invasive biomarkers.	The Sjogren's project will focus on the development of diagnostic biomarkers to provide a molecular characteri zation of the disease spectrum in diverse Sjogren's Syndrome and sicca populations and test for associations with clinical sub-phenot ypes foremost in the salivary gland tissue. The project will also identify blood-based molecular signatures that correlate with salivary gland signatures and clinical sub-phenot ypes for development of minimally invasive biomarkers. Key cohorts from NIDCR, Johns Hopkins and the Oklahoma Medical Research Foundation will contribute patient samples to the project. The plan will focus on spatial transcript omics of glandular tissue (nanoString), serum proteomics (Olink) and autoantibody profiling (Sengenics) in blood to identify and interrogate homogeneous subgroups of patients with clinically defined Sjogren's or those in early development of the disease. The project plan is scheduled to come before the BC Executive Committee for review in late Q1 2021.	Fundraising efforts are underway	TBD

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

National Institute of Diabetes and Digestive and Kidney Diseases

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership-Common Metabolic Diseases [Previously named Metabolic Disorders]	This is a new AMP project within the Accelerating Medicines Partnership umbrella. The AMP was proposed by NIDDK, under the leadership of Drs. Griff Rogers and Phil Smith as a 5-yea program. FNIH is facilitating the development of this proposal with interested companies.	FNIH development team is actively reaching out to private partners (pharmaceutical companies and non-profits) to fundraise for the program. Pending successful fundraising, the program is set to launch in Q1 2021.	Fundraising efforts are underway	TBD
Accelerating Medicines Partnership: Type 2 Diabetes	Leveraging success of the AMP T2D Knowledge Portal, the AMP Metabolic Diseases project will focus on target prioritization and validation for complications of diabetes including kidney disease, liver disease, heart disease, obesity and underlying immunological pathways. A large part of the initiative would involve growing the current portal to include complications-specific tools and visulizations as well as genetic, genomic, biomarker and tissue specific data.	AMP T2D is expected to complete all activities by June 2021. In the last 3 years, the AMP Knowledge Portal has expanded to include other portals in cardiovascular, cerebrovascular, sleep, musculoskeletal and T1D areas. Currently, the KP houses sequencing and traits data from >1.3M samples from across 5 ancestries and geographies, and many cardiometabolic, hepatic and renal traits. We have a new heuristic to predict effector genes, along with additional new tools that allow multiple query-based analyses on these datasets. The portal now features sophisticated tools like an interactive manhattan plot, a genetic variance finder, and genetic risk scores in addition to PheWeb, a sophisticated tool to compare risk loci with associated traits. The final sets of data in will include functional data from kidney, muscle and liver tissues. If approved, AMP CMD will expand on the resource and community developed by AMP T2D.	$21,775,000	Mar-14
Biomarkers Consortium - Mucosal Healing in UC: Definition, Treatment Target and Clinical Endpoints	Ulcerative colitis (UC) is a chronic, relapsing and remitting inflammatory bowel disease (IBD) that affects 249 per 100,000 persons in the United States, and the incidence and prevalence of UC is increasing worldwide. UC is associated with mucosal inflammation in the rectum that may extend proximally to involve part or all of the mucosal lining of the colon. There is currently no community consensus on a method for assessing mucosal healing. The objective of this project is to establish a common methodology for a histologic measurement of a mucosal healing endpoint for treatment of ulcerative colitis (UC) that demonstrates clear prognostic value for long-term outcomes for patients. The project aims to 1) establish the number, location, size, and density of biopsies required to capture variability across the colon and standardize protocols for biopsy collection 2) establish a histolopathologic measurement of mucosal healing that correlates with long-term patient important outcomes 3) establish a machine learning methodology as a validated objective method for scoring of mucosal healing for use in clinical trials, regulatory approvals, and clinical practice.	The primary aim of the project is to establish a common and harmonized methodology to define mucosal healing in ulcerative colitis (UC). The Biomarkers Consortium Executive Committee approved the project plan on December 4, 2019. Fundrasing is complete and exceeded the targeted goal of $3.45M. The project team is comprised of 8 pharma and 2 not-for-pr ofits partners. Final contracting is ongoing with Dr. Noam Harpaz (Mt. Sinai) for an initial clinical study that will help standardize and improve the assessment of disease activity and mucosal inflammation for patients with UC. The initial project kick-off and project team meeting was held on November 29, 2020 with formal project launch scheduled for late-February 2021.	$5,381,856	Jun-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Clinical Evaluation and Qualification of Kidney Safety Biomarkers	The Kidney Safety Project, managed by the Executive Committee of the Biomarkers Consortium, aims to qualify novel biomarkers of drug-induced acute kidney injury. The project is designed to include a learn-and-confirm phase. The learn phase consists of retrospective analyses of mesothelioma patient and healthy volunteer data in order to establish a prioritization for the novel biomarkers that seem most promising for the prospective analyses. The prospective analyses are based on data collected from two observational clinical trials conducted at 4 different sites - 2 with aminoglycosides and 2 with cisplatin - aiming to validate some important biomarkers of acute kidney injury (AKI) that perform better than serum creatinine and BUN (the currently used biomarkers of AKI). This project is funded by 6 pharma companies.	The data adjudication and analyses of the prospective clinical study data remains delayed during the COVID pandemic, awaiting critical discussion with FDA to review the draft Qualification Plan and stability data on 2 of 8 novel biomarkers of acute kidney injury. The project team has used this time to focus on preparing manuscripts on the initial datasets that established the biomarkers used in the prospective study and the levels of protein expression for each that are indicative of acute kidney injury. Data adjudication will be completed using data and clinical data in the early half of 2021 to support the next qualification package.	3,605,778	Jul-11
Biomarkers Consortium - Non-Invasive Biomarkers of Metabolic Liver Disease	The MDSC formed a working group to look at areas of interest for NASH biomarkers. Broad areas include exploration of soluble factors, dynamic tests for liver function, and imaging modalities. The group is looking at a project towards developing credible technologies, other than biopsy, to allow staging and quantification of diffuse liver disease, for which there are currently neither surrogates nor agreed upon outcomes.	Data generation for NIMBLE retrospective study are underway and expected to be completed by April 2021. IRBs are approved for both imaging studies. Ultrasound and MR based imaging studies are likely to recruit participants in February 2021. The NIMBLE program is expected to present their go/no go decision to the MDSC and BC EC by June 2021	12,945,888	Jun-19

NATIONAL
INSTITUTES OF
HEALTH
CLINICAL CENTER

National Institutes of Health Clinical Center

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Clinical Center Drug Donations	An initiative to secure donated medical products/therapeutic agents from pharmaceutical companies for use by the NIH Clinical Center. Receiving these products free of charge enables funds from the Clinical Center's budget to support other clinical research activities.	Lilly is moving forward with providing baricitinib to the CC as a donation rather than as part of a study. Details on the amount and value forthcoming as the donation agreement is finalized.	$16,108,629	Jun-08
Speech Recognition for All	Millions of individuals worldwide have neurodevelopmental or neurological disorders that cause dysarthria, a motor speech disorder that makes speech difficult to understand. These individuals struggle to communicate with others, resulting in significantly reduced independence and quality of life. Automatic speech recognition (ASR) technology provides a potential solution to this problem, as AST software in phones and other devices could function as a translator for these individuals. Individuals could speak, have ASR software understand what was spoken (even when a human could not), and then have the software speak the message in a fully intelligible voice. Such technology would allow individuals with dysarthria to successfully participate in their normal daily activities. This project would establish a public-private partnership between the Rehabilitation Medicine Department of the NIH Clinical Center and top US technology companies in order to accelerate the development of ASR technology for individuals with dysarthria by creating a dataset of dysarthric speech large enough to train deep learning ASR models.	In August 2020, the FNIH Board of Directors' Portfolio Oversight Committee identified several hurdles to successful execution of the project, including the lack of potential funders willing to support the project at the $8.3M level requested by the NIH, and suggested revisions to the collaboration proposal. The Clinical Center provided a revised proposal in October 2020, but its expectations remained inconsistent with key FNIH public-private partnership principles and the project did not move forward.	$0	TBD
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
John Laws Decker Memorial Fund	During his lifetime, Dr. John Laws Decker strived to connect scientific communications around the world to exchange information and accelerate important research. His dedication to education and communication about science makes this annual lecture at NIH an especially fitting tribute to a recognized leader and teacher. The recipient of the annual Distinguished Clinical Teacher's Award given by the NIH Fellows Committee is the invited lecturer as part of the Contemporary Clinical Medicine: Great Teachers Grand Rounds Program.	The John Laws Decker Memorial Lecture took place by Virtual presentation on June 10, 2020. The featured speaker was the recent Distinguished Teachers Award recipient, Dr. Mario Bilusic who spoke on "Personalized Oncology: Are We There Yet?"	$42,910	Jan-03
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Dr. John L. Barr Memorial Fund for Cancer Research	The Dr. John L. Barr Memorial Fund helps to support the Intramural Research Training Award Fellowship Program at the NIH Clinical Center's Pain and Palliative Care Service. The objective of the fellowship is to conduct research on pain and palliative care, and also to encourage young investigators to become more familiar with the importance of this field of study.	FNIH Staff met with Jill Barr to discuss the future of the Fund. Next steps are to obtain an update from Dr. Berman on use of the previous funds.	$25,284	May-04

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Medical Research Scholars Program Class of 2020-2021	The National Institutes of Health (NIH) Medical Research Scholars Program (MRSP) is a comprehensive, year-long research enrichment program designed to attract the most creative, research-oriented medical, dental, and veterinary students to the intramural campus of the NIH in Bethesda, MD. Student scholars engage in a mentored basic, clinical, or translational research project that matches their professional interests and career goals. The MRSP combines and replaces two successful NIH training programs, the NIH-Howard Hughes Medical Institute Scholars and the Clinical Research Training Program.	Scholars arrived on campus in the Fall of 2020. They have completed orientation, selected a mentor, and research activities are underway. Scholars are working under COVID-19 protocols including social distancing. Support for this class of scholars was received from the American Association for Dental Research, Doris Duke Charitable Foundation, Colgate-Palmolive Company, and Mrs. Buffy Cafritz.	$450,000	Jan-19
Medical Research Scholars Program Class of 2021 - 2022	The National Institutes of Health (NIH) Medical Research Scholars Program (MRSP) is a comprehensive, year-long research enrichment program designed to attract the most creative, research-oriented medical, dental, and veterinary students to the intramural campus of the NIH in Bethesda, MD. Student scholars engage in a mentored basic, clinical, or translational research project that matches their professional interests and career goals. The MRSP combines and replaces two successful NIH training programs, the NIH-Howard Hughes Medical Institute Scholars and the Clinical Research Training Program.	MRSP is a year-long residential research immersion program for medical, dental and veterinary students seeking careers as clinician- scientists Requests for funding for the MRSP Class of 2021 - 2022 is underway. A grant from the Doris Duke Charitable Foundation (DDCF) of $350,000 has been received. Requests for renewed funding will be made to Colgate-Pa lmolive, the American Association for Dental Research, and Genentech. Programmatic activities continue with staff of the MRSP currently engaged in efforts to recruit the next class of scholars. Applications were accepted from October 1, 2020 - January 8, 2021.	$350,000	Oct-20
Capital Projects				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Edmond J. Safra Family Lodge (Bricks and Mortar)	The Edmond J. Safra Family Lodge offers a home-like residence for families and loved ones of adult patients who are receiving care at the NIH Clinical Center, a comfortable environment intended to alleviate the incredible burden that accompanies serious illness. The Family Lodge features 34 guest rooms, family gathering areas including living room, dining room, kitchen, playroom, library, exercise room, and telecommuting facilities that allow families to manage their home and business lives during their time at NIH. This project was funded by the Edmond J. Safra Philanthropic Foundation and other generous individual and corporate contributors.	No active campaign at the moment.	$3,270,478	Jan-98
Edmond J. Safra Family Lodge GSK Endowment	The GlaxoSmithKline Endowment supports programs and activities for families staying at the Edmond J. Safra Family Lodge, including services that help residents stay in touch with employers and loved ones.	FNIH is looking into plans on how to best use these funds; proposal to utilize fund to support Lodge Breakfast program.	$1,500,000	Jan-01
Edmond J. Safra Family Lodge Weinberg Endowment	The Weinberg Endowment supports Edmond J. Safra Family Lodge operations and maintenance, ensuring that guests are provided a comfortable home away from home for years to come.	FNIH is looking into plans on how to best use these funds; proposal to utilize fund to support Lodge Breakfast program.	$750,000	Dec-00

Capital Projects				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
John and Elaine Gallin Fund	The Gallin Fund provides support for the Edmond J. Safra Family Lodge and to support clinical research needs of the intramural research program at the National Institutes of Health.	On September 18, 2020, the FNIH named Michael Wilson, M.D., the recipient of the 2020 Trailblazer Prize for pioneering a next-generation diagnostic approach to pinpoint infectious causes of inflammatory conditions of the central nervous system. Visit: https://awards.fnih.org	$167,047	Jan-13
Lifecycle Replacement Plan for the Edmond J. Safra Family Lodge	This project helps the FNIH and the Family Lodge to prioritize maintenance needs, anticipate costs, align resources and plan accordingly. The Lifecycle Replacement Plan strategy for the long-term conservation of the Family Lodge will be implemented in two phases. Phase I is a comprehensive assessment of the Family Lodge, with a maximum allocation of $40,000 for the report. Phase II will be incremental disbursements of funding over a five-year period allocated to the preservation of current Family Lodge standards, with a maximum expenditure of $70,000 per year as informed by the Lifecycle Replacement Plan.	FNIH staff maintain ongoing communications to discuss maintenance items and future needs of the Lodge.	$640,225	Jan-16
Safra Family Lodge - All Programs	The Edmond J. Safra Family Lodge offers a home-like residence for families and loved ones of adult patients who are receiving care at the NIH Clinical Center, a comfortable environment intended to alleviate the incredible burden that accompanies serious illness. The Family Lodge features 34 guest rooms, family gathering areas including living room, dining room, kitchen, playroom, library, exercise room, and telecommuting facilities that allow families to manage their home and business lives during their time at NIH. This project was funded by the Edmond J. Safra Philanthropic Foundation and other generous individual and corporate contributors. Ongoing gifts from donors provide support of the Family Lodge's operations and comfort of its guests. Annual investment income generated by an endowment fund supports program expenses, while the principal remains intact to ensure future funding.	FNIH Advancement continues to receive contributions in support of the Safra Family Lodge-All Programs. Fundraising communicat ions/appeals being considered for Safra Family Lodge during 2021.	$4,079,363	May-05
Tracy's Toy Box Memorial Fund	This fund supports the purchase of toys and activities for children staying at the Edmond J. Safra Family Lodge to help make their time there more comfortable and pleasant. Tracy's Toy Box was established in memory of Tracy Nadel.	Strategy for the future of the Fund is to be determined.	$13,982	Jan-04

NATIONAL
INSTITUTE OF
MENTAL HEALTH

National Institute of Mental Health

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership - Schizophrenia	The proposed AMP SCZ Project Concept aims to establish a system to run proof-of-concept clinical trials that can test biological hypotheses in CHR individuals and in individuals with schizophrenia. In order to establish such a system, AMP SCZ is proposing to leverage NAPLS and EPINET to characterize a large cohort of CHR individuals in terms of polygenic risk scores, brain activity, physiology, behavioral processes, and life experience. Then, with all of this phenotypic data, AMP SCZ will stratify individuals from this cohort into risk pools and will conduct proof-of-concept trials in order to test hypotheses in this population, which will help investigators to determine which markers (1) might be useful in future clinical trials, (2) are useful for stratification, and (3) are treatment responsive. The AMP SCZ partnership may catalyze testing of therapeutic interventions in CHR individuals by (1) validating a set of risk stratification algorithms (e.g., using multimodal biomarkers) to predict outcomes in CHR individuals, and (2) testing whether these predictive algorithms are responsive to compounds contributed by the private sector in proof-of-concept studies. Thus, AMP SCZ will consist of two phases. During Phase 1 (months 0 to 12), AMP SCZ will conduct a meta-analysis of existing biomarkers studies and will select a risk stratification algorithm for use in clinical trials. AMP SCZ must determine whether developing this risk stratification algorithm is achievable using only existing data (e.g., from NAPLS and HARMONY) or will require the consortium to generate prospective biomarker data, perhaps by leveraging EPINET. Next, during Phase 2 (months 12 to 60), AMP SCZ will conduct proof-of-concept clinical trials, test biomarkers for their stratification utility and drug responsiveness, and incorporate biomarker algorithms into already existing and planned clinical trials. In parallel, industry may incorporate one or more of the biomarkers being assessed in CHR subjects by AMP SCZ into FEP or early psychosis trials to help validate a multivariate predictive biomarker.	Following the September 15, 2020 launch of the Accelerating Medicines Partnership in Schizophrenia (AMP SCZ) program, NIMH-funded investigators and private and public partners have successfully engaged in collaborative work to ensure successful initiation of new cohort data collection as outlined in the project plan. Investigators from the two NIMH-funded Clinical High Risk (CHR) Research Networks (Australia n-based PRESCIENT and US-based ProNET) and the Data Processing and Analysis Coordination Center (DPACC) participated in working groups established to facilitate crucial harmonization of measures to be collected across varied biomarker modalities at approximately 43 clinical sites worldwide. Along with representa tives from AMP SCZ private partners providing input to all the working groups, close to 130 subject matter experts in clinical ascertainm ent, patient perspectives, data processing, biomarkers, and functional endpoints worked closely to achieve consensus guidance for the final study design. In January 2021, the AMP SCZ Steering Committee established additional working groups that will focus on: 1. Formalizing the data analysis plan for new cohort data to be collected 2. Developing a AMP SCZ website that will serve as a resource for a broad range of audiences; 3. Leveraging expertise and resources provided by our non-profit private partners to support recruitment efforts; and 4. Provide expert guidance on appropriate sample sizes and anticipated effect sizes. The AMP SCZ Steering Committee established a team to develop the first research article describing the program for publication in peer-reviewed literature. NIMH-funded AMP SCZ investigators are currently anticipating submittal of the final study protocols for approval at the end of Q1 2021.	$16,500,000	Aug-19
Baby Connectome Project	The Baby Connectome Project is one of several programs that build upon the NIH Human Connectome Project (HCP), designed to map the neural pathways that underlie human brain function. The HCP's initial five-year version supported technology development and assessment followed by data collection on a cohort of 1,200 healthy young adults (ages 22-34). The goal of the Baby Connectome is to obtain structural and functional connectivity data for the healthy human brain in the 0 to 5 year age range. The Baby Connectome Project grant was awarded in September 2016 to the University of North Carolina at Chapel Hill, with a sub-award to the University of Minnesota.	Research is ongoing. The project has entered into a one-year no cost extension (NCE). A final report that the FNIH can provide to the donor is expected from the NIMH by December 2021 (about 120 days after the end of the NCE).	$2,939,869	Dec-14

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Longitudinal Proteomic Changes in CSF from ADNI: Towards Better Defining the Trajectory of Prodromal and Early Alzheimer's Disease	The lack of tools for early diagnosis and measurement of disease progression in Alzheimer's Disease (AD) continues to be a major hurdle in AD drug development; the current AD biomarkers do not work in this context. The present study addresses this need by extending the work on promising proteins identified in a previous BC project. The study will measure the rate of change of 5 protein biomarkers within MCI, AD and HC patients, utilizing a multiplexed mass spectrometry-based approach. The proposed longitudinal sample set has at least 3 CSF samples from each individual drawn over a three-year or greater period, as well as available clinical and imaging data. Success within this project could greatly improve progression and treatment monitoring in early Alzheimer's Disease patients. The study is expected to have a duration of 18 months, and results will be available to the public on the Laboratory of Neuroimaging (LONI) website as they become available.	The Longitudinal CSF Proteomics Project has reached the closeout stage following acceptance of the Phase 3 and 4 NPTX2 ELISA Methodology Report by the Project Team and its subsequent upload into the ADNI Laboratory of Neuro Imaging (LONI) public database. Findings and accomplish ments of the project were communicated through targeted social media advertisem ents during the Clinical Trials on Alzheimer's Disease (CTAD) Conference in November 2020. Additionally, the project Writing Group prepared the manuscript for publication in the Alzheimer's and Dementia journal. As next steps for project closeout, the FNIH will finalize and transmit formal closure letters to project funders, project team members, and vendors.	$524,473	Aug-16
Biomarkers Consortium - The Autism Biomarkers Consortium for Clinical Trials (ABC-CT)	The ultimate goal of the project to qualify a set of measures that can be used as stratification biomarkers and/or sensitive and reliable objective measures of social impairment in ASD clinical trials that could serve as indicative markers of long term clinical outcome. The project will support a multi-site study to assess a well-justified set of standardized investigator-administered assessments of domains of social impairment as well as neurophysiological measures (resting state and task-based EEG and eye tracking) that show promise in school age individuals with ASD (ages 6-11) at baseline, 6- and 24-week time points. In addition, at least one task-based EEG and one eye tracking measure from the European Autism Interventions (EU-AIMS) study will be included among the set of proposed biomarker paradigms. The inclusion of these measures will foster harmonization and independent replication of a common subset of biomarker measures in the proposed projects.	All the timepoints were collected for the clinical trial and the data has been cleaned and locked with primary readouts still underway. The N170 and eye-tracking Biomarker Qualification Plans for the FDA are currently being drafted. Closeout activity is underway.	$2,000,343	Sep-15
Deeda Blair Research Initiative Fund for Disorders of the Brain	The Research Initiative Fund will be used for the purpose of funding grants to accelerate innovative research in the field of mental health, the focus shall be to fund basic research, training and novel programs in bipolar disorder, depression, and related psychotic, anxiety and mood disorders. Emphasis should be given to support the most creative investigators as defined and identified by the award selection committee. The members of this committee will have been carefully selected for their experience, wisdom, quality and leadership. It is expected that monies will be disbursed or be fully committed as soon as possible and practical after the establishment of the Research Initiative Fund to ensure high impact and to provide momentum to the research projects selected. These monies are meant to provide highly meritorious researchers with emboldening support to carry out the most novel science. The Research Initiative Fund is not meant to be intensively structured.	FNIH staff received approval from the Blair Scientific Selection Committee to provide awards to support the National Neuroscience Curriculum Initiative (NNCI) and two past recipients of the NIMH Outstanding Resident Award Program (ORAP). In partnership with NIMH, the FNIH created an application and scientific review process for past ORAP recipients. Three individuals were chosen for the Blair Research Initiative's first set of awards, and the awards were fully executed and paid.	$15,480,117	Apr-16

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

National Institute of Neurological Disorders and Stroke

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Parkinson's Disease	The Accelerating Medicines Partnership (AMP) for Parkinson's Disease (PD) is a Public-Private Partnership between the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute on Aging (NIA), the Food and Drug Administration (FDA), Celgene, GSK, Pfizer, Sanofi, Verily and the Michael J. Fox Foundation (MJFF). The AMP PD research plan encompasses a deep molecular characterization and longitudinal clinical profiling of PD patient data and biosamples with the goal of identifying and validating diagnostic, prognostic and/or disease progression biomarkers for Parkinson's disease (PD). AMP PD utilizes well-characterized cohorts with existing biosamples and clinical data that are collected under comparable protocols and using common data elements. The cohorts include MJFF and NINDS BioFIND Study, the Harvard Biomarkers Study (HBS), the NINDS Parkinson's Disease Biomarkers Program (PDBP), and MJFF Parkinson's Progression Marker Initiative (PPMI). AMP is generating broad profiling data on biospecimen from these cohorts. The proposal includes open data sharing of molecular and clinical data generated to enable dissection of new targets, disease subtypes, and the identification of predictive markers for disease progression and disease prognosis.	This program has as an ultimate goal the validation of clinical biomarkers to be used in Phase 2 POC trials. The partnership has 6 private and 3 federal government partner, and 1 nonprofit partner. We have $12M in cash and $2M in kind form Verily for the Knowledge portal. During Q4 2020 period a 1) Additional data and resources now available on the AMP PD Knowledge Platform. The AMP PD Knowledge Platform now provides qualified researchers access to the harmonized rich clinical, genomics, and transcript omics information collected from over 10,000 participants across seven unified cohorts, including those with Parkinson's, Lewy Body Dementia, and control volunteers; 2) Generated targeted proteomic data from 1,496 matched plasma and CSF samples; (3) Samples shipped for untargeted proteomics analyses using Data Independent Acquisition (DIA) Mass Spectrometry; 4) Released an RFP for Proteomics Analyst postion; 5) Continued public website updates and improvements; 6) Submitted a AMP WGS article; and 7) Regularly convened the Steering Committee, Working Groups, and Subgroups to continue progress on the AMP PD resource developement and analyses.	$12,034,400.00	Mar-17
Biomarkers Consortium-Neurofilament as a Fluid Biomarker in Familial Frontotemporal Degeneration	There is a need for reproducible biomarkers that can predict the onset of symptoms of major neurological diseases. Evidence has shown that levels of Neurofilament (Nf) proteins increase in cerebrospinal fluid (CSF) and blood resulting from neuroaxonal damage. A reliable measure of neurofilament in blood would enable identifying changes in the brain at the earliest stages of the disease, preceding the onset of symptoms. This project will evaluate next-generation Nf assays to determine whether peripheral Nf measures are sufficiently robust and reproducible to inform on the selection of patients in a clinical trial. There are currently no therapeutics to treat or prevent FTD and a significant challenge for regulatory approval of new therapeutics is the generalized heterogeneity of the FTD population. Nf could be used to address the heterogeneity of healthy patients with the major genetic causes of FTD; e.g., microtubule-associated protein tau (MAPT), progranulin (GRN), and chromosome 9 open reading frame 72 (C9orf72); enabling the identification of a population at high risk of converting to symptomatic disease. If qualified, this could be a tool to accelerate novel development of disease-modifying therapeutics to prevent or delay the onset of f-FTD symptoms and would lay the groundwork for use in other neurodegenerative diseases.	The BC Executive Committee approved the Project Plan on July 10th, 2020. The Neurofilament Project Development Team (PDT) reviewed assay performance data in a due diligence and prioritized six assays. Final selection of assays will be decided by the funding project team. The PDT has also developed an LOI Writing Subgroup to draft an LOI to the FDA's Biomarker Qualification Program. Fundraising is underway for with Biogen joining the Bluefield Project to Cure Frontotemporal Dementia as a funding partner in this project. The FNIH will draft service agreements in Q1 2021, and once the project is fully funded.	$700,000.00	TBD
Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D.	Dr. Zaghloul's research focuses on using direct human intracranial recordings in patients undergoing surgical treatment for epilepsy to understand these mechanisms, which can provide new and potent understanding of complex neurophysiologic circuitry in the human condition. Funds support a fellow in the lab of Dr. Zaghloul for 2 years and a piece of equipment for the lab.	FNIH has been in contact with NINDS, most recently in June 2015 about when funds might be transferred. NINDS has indicated that they have a Fellow in place and that they will likely be requesting funds be transferred soon.	$290,000.00	Nov-13

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
James T. Wendel Fund	Restricted funds to be received from the estate of James T. Wendel.	Restricted funds to support muscular dystrophy research are anticipated in 2021.	$700,000.00	Oct-20
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
NINDS/CNSF K12 Scholar Awards Program	Beginning in 2016, an early career neurosurgeon will be competitively selected as the National Institute of Neurological Disorders and Stroke Congress of Neurological Surgeons Getch Scholar (NINDS/CNS Getch Scholar). The Scholar, appointed as part of a larger, ongoing NINDS national career development program, will receive two years of funding to help launch a dual, clinical-research career for neurosurgeons who possesses unique clinical and research skills that identify them as the next generation of neurosurgical leaders. This program has been expanded to support an additional K12 scholar award.	Due to COVID-19, support for the 2020-2021 Scholars has been delayed.	$400,000.00	TBD
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
CarMollNat Muscular Dystrophy Endowment	Carol-Ann Harris will create an Endowment to fund research into one or more of the major types of Muscular Dystrophy at the Neurogenetics Branch of the NINDS.	FNIH staff continuing stewardship of the CarNollNat Muscular Dystrophy Endowment.	$4,074,852	Jul-13
Edna Williams Curl & Myron R. Curl Fund for Multiple Sclerosis Research	As specified in this bequest to FNIH, interest income from the Edna Williams Curl and Myron R. Curl Fund, established in 2007, is designated to support multiple sclerosis research at NIH.	Per the terms of the endowment agreement, once sufficient interest income has accrued, the FNIH will use the income to support NINDS research in the field of multiple sclerosis. When sufficient income is available, the FNIH will discuss possible uses for the fund with NIH.	$60,253	Aug-07
Robert Whitney Newcomb Memorial Lecture and Internship	The Robert Whitney Newcomb Memorial Fund was established by the family to remember Dr. Newcomb, who began his scientific career at NIH as a high school summer intern in a laboratory at the National Cancer Institute. The Fund endows an annual lecture by a recognized expert in neuroscience, selected by the National Institutes of Neurological Disorders and Stroke (NINDS) at NIH. Honoring Dr. Newcomb's own experience, it also provides for internships for high school students and fellows at NINDS.	The current postbac will complete this year's work, and move on to grad school in 2021. Dr. Wray is considering reviewing applications for a replacement. The postponed Newcomb Lecture is set to take place virtually on May 3, 2021.	$1,264,475	Jan-00

OTHER

Other

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Abrams Charitable Fund	The Abrams Charitable Trust provides financial support to the FNIH to support translational research directed at treatment and/or cure of neurodegenerative diseases with a focus on the various forms of common dementias. The research must be translational in nature and must be directed at finding treatments and/or cures for neurodegenerative diseases focused on, but not limited to, the common causes of dementia such as Alzheimer's disease, Parkinson's dementia, Lewy body dementia, Frontotemporal dementia, etc. Other neurodegenerative disease such as ALS, MS, prion disease and other degenerative motor neuron diseases are also eligible for funding.	A call was held with FNIH staff, Dr. Youle, and Mr. Rosencranz in August 2020 to further describe their research performed with the Abrams Charitable Trust's support from the previous year. Mr. Rosencranz and FNIH staff continue to make periodic updates to Dr. Abrams.	$34,753	Oct-18
Biomarkers Consortium - Contributing Membership	The Biomarkers Consortium engages a broad spectrum of stakeholders and funders (which may include NIH, FDA, industry, associations and foundations) to support the infrastructure required to facilitate the development of a variety of biomarkers projects. In addition to creating and supporting an infrastructure for broad, cross-sector communication and consensus and identifying areas of promising research, the Biomarkers Consortium also facilitates joint financial investment in the identified research activities each of which emerge as a distinct scientific initiative under the Consortium administrative "umbrella."	Currently, the Biomarkers Consortium (BC) has 63 contributing members. In Quarter 4 of 2020, all activities were held via teleconference due to COVID-19 including the Executive Committee teleconference on October 23. Steering Committee teleconferences were held by the Neuroscience Steering Committee (NSC) on October 14 and December 11, the Metabolic Disorders Steering Committee (MDSC) on November 18, the Inflammation and Immunity Steering (IISC) Committee on December 1, and the Cancer Steering Committee (CSC) on December 2. In addition, the CSC held its annual two day symposium on December 3-4.	$25,452,459	Mar-05
Charles A. Sanders Legacy Fund (Project Legacy)	The Charles A. Sanders Legacy Fund provides the flexibility for FNIH to incubate new ideas, to enable the FNIH to provide oversight and seed funding for novel, transformative scientific initiatives and launch innovative, creative initiatives that will continue to enhance biomedical research. This investment will also allow FNIH to react rapidly and responsibly to new NIH requests under unique circumstances: unexpected budget reductions like sequestration, for example, or when immediate funding is critical, such as during the Ebola crisis. Lastly, the Fund enables FNIH to maintain the Charles A. Sanders Partnership Award to recognize an outstanding, top-contributing partner each year.	On September 18, 2020, the FNIH named Anthony S. Fauci, M.D., as the recipient of the 2020 Charles A. Sanders, M.D., Partnership Award for his legacy of leadership and ongoing support of FNIH programs propelling research in lethal infectious diseases, most recently for COVID-19. Visit: https://awards.fnih.org	$3,013,788	May-15

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Consensus Pathway for Gene Drive in Mosquitoes	Research is ongoing to use natural or engineered gene drive systems to create a low-cost, sustainable tools for controlling transmission of vector-borne diseases. The goal is to reduce or eliminate vector mosquitoes, or render them less competent to transmit pathogens. Either outcome should contribute to disease reduction. The CRISPR/Cas system provides a molecular tool to create driving transgenes. Not yet optimized, such mosquitoes have been developed with the intent of testing in the field. Guidance and oversight mechanisms are needed to help ensure safe use of the technology before field testing begins. This project convened a panel of prominent experts to think through resources and activities needed to ensure safe and efficient field testing of Anopheles gambiae mosquitoes modified with low threshold gene drive systems for the elimination of malaria in Sub-Saharan Africa. Recommendations are intended to inform researchers, funders, and regulators, and policy makers.	The FNIH established a multidisciplinary Core Working Group (with expertise in malaria transmission, vector control, epidemiology, ecology, evolutionary biology, biosafety, bioethics, global health and clinical trial design) to develop consensus recommendations on requirements for safe, ethical and efficient field testing of mosquitoes modified with driving transgenes. The report – "Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group" – was published in 2018 (doi: https://do i.org/10.42 69/ ajtmh.18 -0083). In 2020, the FNIH continued collaborating with the World Health Organization (WHO) to update the WHO 2014 publication "Guidance framework for testing of genetically modified mosquitoes" with gene drive-specific guidance based on the 2018 "Pathway to deployment ..." recommendations. The updated draft is with the WHO for review and further editing to meet their needs. The final WHO product will have a positive influence on the activities of a variety of stakeholders (researchers and developers, regulators and policy makers, and funders).	$1,836,845	Jul-16
FNIH Travel support for NIH Scientists	This travel grant is used to arrange for and provide support to National Institutes of Health (NIH) personnel to participate in technical, strategic and advisory meetings as needed and requested by the Bill & Meinda Gates Foundation.	The grant term was extended to December 31, 2023. Due to the pandemic, all activities that would have led to additional travel were halted in March 2020.	$928,440	Aug-13
GeneConvene Global Collaborative	The GeneConvene Global Collaborative's mission is to support coordination among stakeholders that enables the development and dissemination of scientifically rigorous information, consensus best practices guidance and standards, and administrative, regulatory and technical advice and training that will advance responsible research, development and, if warranted, implementation of gene drive technologies to eliminate vector borne diseases, with a focus on malaria in Africa, and improve public health.	GeneConvene continued to aggregate and disseminate information about gene drives through the Regulatory and Policy Considerations webinar series, the Virtual Institute website and newsletter, and social media channels. GeneConvene presented at and participated in international meetings about global health innovation and vector control, advanced a program to collect stakeholder input on development criteria, and planned a series of panels on stakeholder engagement.	$23,058,806	Jul-20
Pandemic Response Fund	In response to the COVID-19 crisis, the FNIH has established a "Pandemic Response Fund". Gifts to the Fund will be used to support the NIH's efforts to end the threat from COVID-19 and to better prepare the United States to defend against future pandemics.	FNIH continues to receive contributions in support of the Pandemic Response Fund.	$329,628	Mar-20

Research				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
The Partnership to Accelerate Novel TB Regimens	The Partnership to Accelerate Novel TB Regimens (PAN-TB) is a global collaboration of philanthropic, non-profit and private sector organizations, who are working together to accelerate the development of novel TB treatment regimens for all TB patients. The FNIH will provide project management support for multiple working groups and governance bodies and will convene three annual meetings for the consortium during this project.	No update at this time (still negotiating the NDA).	$1,270,875	Jun-20
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
FNIH 25th Anniversary	In 2021, the FNIH is celebrating its 25th anniversary by reinforcing its position as a thought leader, raising brand awareness and further cultivating relationships with our partners, stakeholders and supporters. Across the Foundation, such activity is being conveyed through the enhancing or modified execution of new and exciting FNIH projects, events and fundraising efforts, in addition to a redesigned website.	Special programs and other initiatives for this occasion are planned.	Fundraising efforts are underway.	Jan-21
Pamela Anne Cafritz Renal Cell Carcinoma Award Fund	The Fund is designed to support the development of highly innovative approaches and technologies aimed at addressing kidney cancer. The Award will be disseminated as a special call for proposals at the National Cancer Institute, under the leadership of the Director of the Center for Cancer Research or his/her designee. The Award seeks to provide an investigator enabling research support in hopes of reducing the proliferation of and death from this disease.	FNIH staff continued to steward this project as payments were received to continue the award.	$500,000	Jan-18
2020 FNIH Award Ceremony	In 2020 FNIH will hold its eighth annual award ceremony at which it will present the Lurie Prize in Biomedical Sciences.	Due to the pandemic, the FNIH celebrated Lurie Prize winner, Dr. Aviv Regev in a virtual ceremony. Visit: https://awards.fnih.org	$330,000	N/A
2021 FNIH Award Ceremony	In 2021 FNIH will hold its ninth annual award ceremony at which it will present the Lurie Prize in Biomedical Sciences.	Planning meetings to determine program format for the 9th annual FNIH Award Ceremony to begin in January 2021.	Fundraising efforts are underway.	TBD
The Lurie Prize in Biomedical Sciences	In 2013, FNIH presented the first Lurie Prize, an annual award recognizing outstanding achievement by a promising young scientist in biomedical research. The Prize amount is $100,000, to be used as the recipient chooses. It is made possible by a generous gift from FNIH Board member Ann Lurie. The winner is selected by a jury of six distinguished biomedical researchers, chaired by Solomon H. Snyder, M.D., Distinguished Service Professor of Neuroscience, Pharmacology & Psychiatry, The Solomon H. Snyder Department of Neuroscience at Johns Hopkins University and Vice Chairman for Science of the FNIH. Past Lurie Prize winners are Dr. Ruslan Medzhitov (2013), Dr. Jennifer Doudna (2014), Dr. Karl Deisseroth (2015), Dr. Jeannie Lee (2016), Dr. David Sabatini (2017), Dr. Zhijian "James" Chen (2018) and Yasmine Belkaid, Ph.D (2019).	On June 18, 2020, the FNIH named Aviv Regev, Ph.D., winner of the 2020 Lurie Prize in Biomedical Sciences for laying the groundwork for the field of single-cell genomics and spearheading leading-edge technologies that enable a sharper perspective on human cells and applying them to revolutionize understanding of biology and disease. Visit: https://awards.fnih.org	$1,000,000	Nov-11

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Notkins Biomedical Research Fund	Dr. Notkins' 58-year career at the NIH includes publishing approximately 430 scientific papers, serving as editor of five books, and authoring three patents. As a capstone to this service, Dr. & Mrs. Notkins wish to provide funding for small, two-day workshops with the aim of gathering participants to discuss basic science issues pertaining to the biology and pathogenesis of disease ("Workshops").	FNIH Staff reached out to Dr. and Mrs. Notkins to check in for planning the first inaugural Notkins workshop.	$1,200,000	Jun-18
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2020)**	**(Anticipated) Launch Date**
Norman P. Salzman Memorial Award and Lecture in Virology	Dr. Norman P. Salzman's family, colleagues and friends remember the legacy of this noted pioneer in molecular biology through contributions to the Salzman Memorial Fund, which supports the annual Norman P. Salzman Memorial Award and Symposium in Virology. The half-day symposium addresses key topics in virology and immunology and presents an award to a young researcher, in recognition of Dr. Salzman's mentorship of so many young scientists. In 2008, the Salzman Memorial Fund celebrated its 10th anniversary.	The 22nd annual Salzman Memorial Symposium and Award took place virtually on November 9, 2020.	$235,763	Jan-99

Tab Five
Donors Report

FNIH 25
Foundation for the
National Institutes of Health

Donors Report

The FNIH acknowledges and thanks each of its donors, whether they are an individual, not-for-profit, foundation or corporation. Their generosity ensures that the FNIH has the essential resources required to advance a wide variety of pacesetting and innovative research, training and education initiatives. While unrestricted gifts allow the flexibility to use donations where they are urgently needed, restricted gifts serve a specific area of research. Other donors choose to establish funds and endowments to pay tribute to their loved ones.

1. Individual Donors by Program Supported
2. Organizational Donors by Program Supported
3. Donor and Funding Partner Selection Criteria

2020 FNIH Award Ceremony

Robert Balthaser and Ricardo C. Araneda, Ph.D.	$500
Buffy Cafritz	$5,000
Eileen and Jack Connors, Jr.	$10,000
Dr. and Mrs. Marijn Dekkers	$2,000
James H. Donovan	$10,000
Drs. Maria & Ernesto Freire	$2,000
Willard Hillegeist	$500
William M. and Elizabeth C. Kelly	$500
Julie Bell Lindsay	$10,000
Mr. and Mrs. Paul M. Montrone	$25,000
Gilbert S. Omenn, M.D., Ph.D. and Martha A. Darling	$5,000
Dame Jillian Sackler	$10,000
Charles A. Sanders, M.D. and Ann E. Sanders	$2,000
Fred A. and Donna Seigel	$25,000
Solomon H. Snyder, M.D.	$7,000
Russell W. Steenberg and Patricia Colbert	$10,000

Alzheimer's Disease Neuroimaging Initiative 3

Jeffrey Chow	$500
Philip and Nancy N. Lee	$300
John Madden, Jr.	$1,000
Mr. Mehdi Nafissi and Dr. Ann F. Welton	$500
Mary Anne Schofield	$6,000
Robert J. Stets, Jr.	$5,000
Joel Yesley	$420

Adam J. Berry Memorial Fund

Joseph N. and Michie Flanz	$500
Henry L. Hecht	$500
Lori A. Rolnick	$300

Biomarkers Consortium Membership

Arlene L. Feit	$360

Deeda Blair Research Initiative Fund for Disorders of the Brain

Anne S. Goldrach	$30,000
Alan W. Kornberg and Harold Koda	$5,000
William and Stephanie Marra	$250
Michael Jefferson Meagher	$50,000
Virginia Schirrmeister	$20,000
Amy K. Wilfert	$1,000

BRCA Challenge Fund

Dionne Beasley	$300
Andrew and Elyse Steinhaus	$500

Pamela Anne Cafritz Renal Cell Carcinoma Award Fund

Buffy Cafritz	$100,000

Cancer Research Fund

Anonymous	$315
Martin Benz	$388
Diane Brinkley	$268
Matthew Scher and Barbara Lazio	$5,000
Robert J. Stets, Jr.	$5,000

CarMollNat Muscular Dystrophy Endowment

Carol-Ann Harris	$10,665

Michael T. Davis Fund

Estate of Michael T. Davis	$120,609

Follicular Lymphoma Research Fund

Paula L. and William C. Bradley	$500
Steve and Chris Wilsey	$5,000

Futures Fund

Estate of David P. Brown	$813,994
Mr. and Mrs. Joel S. Marcus	$50,000
Steven and Jann Paul	$397,633

John and Elaine Gallin Fund

Robert L. and Janice Diamond	$10,000

Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.

Eric J. and Susan Hatch	$250
William Morley and Caroline Trahan	$5,000

Kovler Prize for Excellence in Science Journalism

Peter and Judy Kovler	$100,000

Lurie Prize

Ann Lurie	$100,000

Medical Research Scholars Program

Buffy Cafritz	$30,000

Robert Whitney Newcomb Memorial Fund

Bob and Sally Newcomb	$20,592

Dean R. O'Neill Renal Cell Cancer Research Fund

Robert Balthaser and Ricardo C. Araneda, Ph.D.	$100
Krista Curtiss	$250
Alicia Emerson	$1,000
Margaret Gavin	$250
John L. and Mary Emma C. Hoye	$25
Anne Kelly	$250
John T. Langford	$250
Mr. and Mrs. Brian R. O'Neill	$1,000
Matthew W. and Erica O'Neill	$1,000

Susanne N. O'Neill	$3,000
John and Katrina Rogers	$2,500

Pandemic Response Fund

Robert Abshire	$500
Robert Balthaser and Ricardo C. Araneda, Ph.D.	$100
Buffy Cafritz	$15,000
Ruth E. Caputo	$250
Kenneth J. Chang and Julia Chang	$1,000
Caroline M. Devine	$500
Laren Friedman	$100
Nancy K. Fugina	$15,000
Peggy J. Gerlacher	$500
Michael and Joan Gottlieb	$50
Jeffrey Hicke	$1,300
Donald Hill and Carolyn Ross	$100
John L. and Mary Emma C. Hoye	$25
Hale G. Lamont-Havers	$400
Helen R. Litt	$1,000
Patrick and Barbara McGarey	$2,400
Cheryl L. Melencio	$100
Ari and Abbey Meltzer	$100
Joanne Morse	$20
Morton L. Moss, M.D.	$250
Jodie Mussio	$500
Eric T. Nygaard	$1,200
Sarah Palamara	$1,000
Jennifer Pohlhaus	$380
Joseph A. Rinaldi	$500
Jennifer Rosenbluth-Stoll and Peter Stoll	$25
Mary Anne Schofield	$500
Edward A. Seidel, M.D.	$1,000
Fred A. and Donna Seigel	$25,000
Dorina Sepulveda	$50
Xinzhuan Su, Ph.D.	$500
Suresh and Feroza Subramani	$250
Brendan Sullivan	$250
Thomas Szuba	$250
Michelle Thomas	$500
William, Zani and Aycen Tolentino	$50
Bonnie Townsend	$500
Janet Vessotskie	$500
Roger Weisman	$1,000
Julie and Howard Wolf-Rodda	$50
Lucas and Katrina Yun-Nikolac	$200
Dr. Xiaowei Zhuang and Dr. Hazen Babcock	$10,000
George Ziga	$250

Piatigorsky Basic Science Lecture and Award

Dr. and Mrs. Joram Piatigorsky	$400,000

Edmond J. Safra Family Lodge

Robert R. and Katherine F. Bair	$500
Dr. and Mrs. James E. Balow, M.D.	$800
Robert Balthaser and Ricardo C. Araneda, Ph.D.	$100
Daniel Cunningham and Mary Hennessey	$1,000
Gene and Esther Gorman	$1,100
Chris and Laura C. Hazzard	$1,000
Patricia S. Kohlen	$14,000
Reverend and Mrs. Robert H. Naylor	$500
Michael V. O'Connell	$500
Matt and Robyn Nichols Painter	$2,000
The Relias Family	$250
Barbara Santos	$1,511
James Schroering	$500
Daniella Schwartz	$500
Kaartik Soota, M.D.	$500
Susan M. Weinert	$500
Kathleen Westmoreland	$4,000

Norman P. Salzman Memorial Fund

Stanley and Eve Geller	$1,000
Lenore R. Salzman	$2,500

Charles A. Sanders Legacy Fund - Project Legacy

John and Sandra Atkins	$2,000

Solarz Memorial Fund

The Honorable and Mrs. Kenneth Adelman	$250
The Honorable and Mrs. Don Bonker	$500
Mary Boyle	$500
Keith F. and Alison Burrows	$600
Donald Burrows	$1,000
Rabbi Steven Denker	$500
Randy K. Glantz	$5,750
Margaret Grieve	$2,000
Gary and Lynn Grossman	$250
Eric Hirschhorn and Leah Wortham	$1,000
Eleanor Holtzman	$6,000
Josh J. Howard	$500
Franz Leichter	$250
Howard H. and Jacqueline K. Levine	$1,000
Avrom Robin	$250
Scylla Stanton	$250

Stephen E. Straus Distinguished Lecture

James M. Felser, M.D.	$1,267

Temporarily Restricted

Anonymous	$250
John Bertschy	$5,000
Marc and Debbie Breslawsky	$25
Annette L. Nazareth and Roger W. Ferguson, Jr.	$25,000
Julie Bell Lindsay In memory of T. Douglas Lindsay	$1,000
Eric T. Nygaard	$1,037
Lorene Steinberg	$500
Robert J. Stets, Jr.	$10,000
Katherine J. Toothman	$1,500

Unrestricted

Robert Abshire	$250
Charles and Lynn Alexander	$500
Stephen and Sharon Alpert	$300
Jeffrey D. and Ann Anderson	$250
Anonymous	$35,937
William Aughenbaugh, M.D.	$1,000
Dr. Nadarajah Balasubramanian	$1,000
Robert Balthaser and Ricardo C. Araneda, Ph.D.	$1,200
Jean Balutanski	$400
Jack D. Barchas, M.D. and Rosemary A. Stevens, Ph.D.	$250
Ann Beck	$250
Joan Beck	$250
Ronald and Barbara Berke	$2,500
Jon H. Beusen and Denise D. Beusen, Ph.D.	$450
James K. and Deborah M. Bieging	$500
Will and Berta Blades	$400
Mrs. William McCormick Blair, Jr.	$500
Laird S. Bloom	$250
John M. and Sharon A. Bremer	$2,000
Marc and Debbie Breslawsky	$1,500
Manson K. Brown	$250
John S. Buchignani, M.D.	$350
Alex Burkart	$250
Lili C. Byers	$400
Buffy Cafritz	$5,000
Raymond and Bonnie Carlson	$250
Dan Balliet and Jan Carlson	$500
Marie Carota	$250
Gina D. Chalmers	$2,500
Joonhao Chuah	$250
Ralph H. and Karen K. Craft	$5,000
B.A. Dass	$600
Stacy F. Davis	$500
Drs. Paul J. and Faith B. Davis	$250
Rosemary Dawicki	$300

Dr. and Mrs. Marijn Dekkers	$50,000
Mark C. Donaldson	$250
James H. Donovan	$10,000
Ashish Doshi	$1,000
Ronald Early	$500
Roland D. Eavey	$500
Drs. Howard J. Eisen and Judith E. Wolf	$500
Donald R. Elrod	$250
William Enright	$250
Ronald G. Evens, M.D.	$1,000
Faye Fager	$500
Susan E. Finley	$2,000
Jeffrey and Marilyn Finn	$500
Drs. Maria & Ernesto Freire	$5,000
Laren Friedman	$590
Elizabeth Garabedian	$250
Hannah Garrick	$300
Thomas Gasparini	$300
James and Karen Gavic	$1,500
Martin Gellert, Ph.D.	$250
Keith Gendler	$670
Teresa M. Gillen	$300
James K. Gilman, M.D.	$3,000
Barry H. Ginsberg, M.D.	$250
Theodore N. Giovanis, M.B.A.	$5,000
Leonard M. and Cynthia A. Glassman	$1,000
Gregory Goers	$300
Drs. David Golan and Laura Green	$2,000
Michael and Joan Gottlieb	$1,200
Kenneth S. Graff, M.D.	$500
Sam D. Graham, M.D. and Jane O. Graham	$250
Randall and Holly Griffin	$750
Estate of Linford M. Hallman	$15,000
Thomas and Charlene Harty	$500
Dr. and Mrs. Paul L. Herrling	$1,000
Donald Hill and Carolyn Ross	$275
Renata Hoffstetter	$357
Drs. Peter K. and Susan F. Honig	$1,000
Susan C. Horowitz	$500
Shirley F. Howe	$1,000
John L. and Mary Emma C. Hoye	$529
Harold and Kay Huston	$6,050
Dr. and Mrs. Thomas R. Insel	$10,000
Yoshiki Ishihara	$400
Stephanie L. James, Ph.D.	$500
Laura Jansen	$500
James F. and Gudrun Jeffrey	$500
Natalie Jimenez	$250

Robert S. and Raissa H. Johnson	$400
Richard Jonas and Katherine Vernot-Jonas	$500
Harris Kaplan	$500
Anne Killingbeck	$500
James C. Kincannon	$700
Alice Klein	$275
Teresa and Kevin Klock	$1,000
Douglas M. and Lynn C. Klock	$500
Mark and Cathy Knepper	$250
Ronald L. Krall, M.D. and Susan J. Krall	$1,000
Jeremy Krasner	$4,000
Paul and Nancy Kurland	$300
Lisa Kuzel	$5,500
John Larabee	$600
Aleah Laxton	$335
Philip and Nancy N. Lee	$600
Dr. and Mrs. Lewis A. Lipsitz	$250
Edison T. Liu, M.D., Ph.D. and Margaret B. Liu	$1,000
Judy Locke	$500
Gary L. and Karen E. Ludwig	$500
Krystal Maguire	$1,400
Mrs. Marlene Malek	$1,000
John F. Malmros and Rosemary F. Contin	$500
Paul D. Manca, J.D.	$1,500
Kenneth D. Mandl	$250
Michele A. Marchand	$1,000
Mr. and Mrs. Joel S. Marcus	$50,000
Anne Alexander Marshall, Ph.D. and Davis Marshall	$250
John and Stacy Martin	$2,000
Cathy Martin	$250
Catherine Master	$1,000
Steve and Sherry Mayer	$10,000
Michael Mayhew	$250
Torrey McClary	$250
Laurence McMillan	$275
Cheryl L. Melencio	$240
Ari and Abbey Meltzer	$500
Richard Meltzer	$500
Joseph Menetski, Ph.D.	$1,200
Raymond Michael	$1,500
Judith Miller	$300
Sheila Mills	$500
Nancy Milovic	$575
Jake Morgan	$633
John M. Morrow	$1,000
Joanne Morse	$360
Rajeev S. and Neeta R. Motiwala	$250
Nabil A. Moufarrej, M.D.	$1,000

Jeffrey Nelson	$465
Jonathan R. Oates	$600
Paul and Cindy Obermeyer	$650
Gilbert S. Omenn, M.D., Ph.D. and Martha A. Darling	$25,000
Sheela Pai Cole	$2,500
Chang H. Paik	$750
Sarah Palamara	$1,000
Farhan Panthaki	$500
Brian Park	$1,200
Kunal Patel	$5,000
Marilyn H. Paul	$1,100
Joseph G. Perpich, M.D., J.D. and Cathy J. Sulzberger	$1,000
Marshall and Kathy Peterson	$275
Mr. and Mrs. Stephen Peth	$1,500
Robert and Paula Petterson	$1,700
Rebecca Phinney	$500
Eric F. Polhamus	$1,000
Mahomud Pradhan	$500
Benjamin Proctor	$301
Helen R. Quill, Ph.D.	$500
Sunny Raspet	$10,500
Michael J. Richman	$250
Curt and Linda Rodin	$5,000
Andrew Rohr	$1,000
Robert A. and Marjorie Rosenberg	$2,000
Jennifer Rosenbluth-Stoll and Peter Stoll	$650
Sidney Rosenzweig	$250
Stanley O. Roth	$500
Dame Jillian Sackler	$10,000
Carol A. Saferstein	$500
Charles A. Sanders, M.D. and Ann E. Sanders	$25,000
Michael Santos	$500
Dr. and Mrs. George Schneider	$250
Darren Schneider	$250
Benjamin Schwartz	$250
Dorina Sepulveda	$220
Norman E. Sharpless, M.D.and Julie Sharpless, M.D.	$1,000
Robert B. and Tammy Renee Sher	$500
Michael Shields	$250
Richard I. and Anastasia Smith	$1,000
Solomon H. Snyder, M.D.	$5,000
Nina K. Solarz	$2,000
Drs. Thomas A. Steitz and Joan A. Steitz	$500
Paul Stoffels, M.D. and Katelijne Bruurs	$25,000
Michael Sullivan	$400
Anthony Tassone	$250
Samuel O. Thier, M.D. and Paula Thier	$500
Christopher A. and Elizabeth Thoma	$850

William, Zani and Aycen Tolentino	$600
Anne S. Tsukuda	$1,000
Arlene Urquhart	$300
Harold E. Varmus, M.D.	$250
Jon and Kristin Vaver	$1,000
Anthony E. Vellek	$250
Ellyn S. Wagner	$500
Eric and Natalie Wannamaker	$500
Paula J. Warrick, Ph.D.	$720
Robert C. Watson and Debra D. Petersen	$500
Dennis E. and Jamie A. Webb	$1,000
Jonathan Weintraub	$250
Roger Weisman	$100
Theodore and Katherine Wells	$500
Sara Lou Whildin	$2,500
David Wholley	$1,000
Stewart K. Wilson	$1,000
Gregory Winkelman	$280
Julie and Howard Wolf-Rodda	$1,015
Richard G. Wyatt, M.D. and Linda S. Wyatt, Ph.D.	$2,000
Lucas and Katrina Yun-Nikolac	$750
Elias A. Zerhouni, M.D. and Nadia Zerhouni, M.D.	$10,000
Daniel Zhao	$1,000
Botao Zhu	$1,000

2020 FNIH Award Ceremony

Alexandria Real Estate Equities, Inc.	$50,000
BDO USA, LLP	$2,000
BEAR Construction Company	$5,000
Bevilacqua & Sons, Inc.	$2,500
W. Bradley Electric, Inc.	$2,000
CBRE - Denver	$2,500
Cleary Gottlieb Steen & Hamilton LLP	$10,000
Davis Polk & Wardwell LLP	$5,000
Eastdil Secured	$10,000
Goulston & Storrs PC	$10,000
Metcor/LSI	$2,000
Morgan Stanley & Co. Incorporated	$10,000
Jack O'Brien Telos Fund	$5,000
Omega World Travel Inc.	$2,000
Paramount Group	$10,000
Paul, Weiss, Rifkind, Wharton & Garrison LLP	$10,000
Peacock Construction	$2,500
ROCHE	$50,000
Sullivan & Cromwell LLP	$5,000
SunTrust Banks, Inc.	$5,000
UCB, Inc.	$5,000

2020 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers

Alzheimer's Association ®	$25,000
The Association for Frontotemporal Degeneration	$5,000
Avanir Pharmaceuticals Inc.	$5,000
Biogen	$10,000
Home Instead Senior Care	$5,000
The Shiley Foundation	$10,000

Abrams Charitable Fund

The Jeffrey A. Abrams and Rosalyn L. Abrams Charitable Trust	$9,563

Accelerating COVID-19 Therapeutic Interventions and Vaccines

National Institutes of Health	$3,614,477

Accelerating Medicines Partnership - Alzheimer's Disease 2.0

Alzheimer's Association ®	$2,690,000
GlaxoSmithKline	$2,690,000
Takeda Pharmaceutical Company Limited	$2,690,000

Accelerating Medicines Partnership - Autoimmune and Immune-Mediated Diseases

Arthritis Foundation	$100,000

Accelerating Medicines Partnership - Common Metabolic Diseases

Eli Lilly and Company	$1,700,000

Accelerating Medicines Partnership - Gene Therapy Design Phase

Bayer AG	$15,000
Boehringer Ingelheim Pharmaceuticals, Inc.	$15,000
Bristol-Myers Squibb	$15,000
Eli Lilly and Company	$15,000
Novartis Pharmaceuticals Corporation	$15,000
Pfizer Inc.	$15,000
ROCHE	$15,000
Sanofi	$15,000
UCB, Inc.	$15,000
Ultragenyx Pharmaceutical	$15,000

Accelerating Medicines Partnership - Heart Failure Design Phase

Amgen Inc.	$20,000
Bayer AG	$20,000
Boehringer Ingelheim Pharmaceuticals, Inc.	$20,000
Cytokinetics, Inc.	$20,000
Ionis Pharmaceuticals, Inc.	$20,000
Novartis Pharmaceuticals Corporation	$20,000
Novo Nordisk A/S	$20,000

Accelerating Medicines Partnership - Rheumatoid Arthritis, Systemic Lupus Erythematosus

GlaxoSmithKline	$1,380,000

Accelerating Medicines Partnership - Schizophrenia

American Psychiatric Association Foundation	$300,000
Boehringer Ingelheim Pharmaceuticals, Inc.	$1,500,000
Johnson & Johnson	$1,500,000
National Alliance on Mental Illness	$300,000
One Mind	$300,000
Otsuka Pharmaceutical Co., Ltd.	$1,500,000
Wellcome	$4,021

ADNI - Amyloid PET Early Frames Add on Study

Johnson & Johnson	$50,000

Alter Fund

Bossak-Heilbron Charitable Foundation	$5,000

Alzheimer's Disease Neuroimaging Initiative 3

Alector, Inc.	$10,000
Alzheimer's Association ®	$200,000
Araclon Biotech, S.L.	$10,000
Bioclinica, Inc.	$25,000
Biogen	$100,000
Cogstate Ltd	$10,000
Denali Therapeutics Inc.	$10,000
DiamiR	$10,000
Eisai Inc.	$100,000

EUROIMMUN AG	$10,000
FUJIFILM Corporation	$25,000
Hewlett Packard Enterprise	$500
Invicro, LLC	$16,667
IXICO Technologies Limited	$16,667
Johnson & Johnson	$400,000
Life Molecular Imaging	$10,000
Eli Lilly and Company	$200,000
Lundbeck	$100,000
MagQu Co., Ltd.	$10,000
Merck Sharp & Dohme Corp.	$400,000
PeopleBio, Inc.	$10,000
ROCHE	$400,000
Saladax Biomedical, Inc.	$10,000
Takeda Pharmaceutical Company Limited	$200,000

Biomarkers Consortium (BC) - 2020 Cancer Steering Committee Annual Scientific Symposium

Adaptive Biotechnologies Corporation	$25,000
Bayer AG	$5,000
Genmab US, Inc.	$5,000
Johnson & Johnson	$10,000
Pfizer Inc.	$25,000
ROCHE	$5,400
Sanofi	$5,000
Takeda Pharmaceutical Company Limited	$5,000

BC - A Novel Total Lesional Automated Computerized Imaging Platform, Biomarker, and Predictive Model for Metastatic Prostate Cancer

Johnson & Johnson	$100,000

BC - ctDNA Reference Material

AstraZeneca Pharmaceuticals LP	$103,215
Johnson & Johnson	$103,215
Merck Sharp & Dohme Corp.	$103,215
PerkinElmer Inc.	$100,000
Pfizer Inc.	$77,411
ROCHE	$103,215
SeraCare Life Sciences	$85,400
Thermo Fisher Scientific Inc.	$87,902

BC - Inflammatory Markers for Early Detection and Subtyping of Neurodegenerative Disorders

Biogen	$100,000
Johnson & Johnson	$177,500
Regeneron Pharmaceuticals, Inc.	$120,000

BC - Markers of Cachexia in Oncology

Pfizer Inc.	$350,000

BC - Membership

AbbVie Inc.	$279,000
ADx NeuroSciences	$10,000
Alkermes, Inc.	$15,000
Amgen Inc.	$150,000
AMRA Medical	$10,000
The Association for Frontotemporal Degeneration	$5,000
Association for Molecular Pathology	$5,000
Astellas Pharma Inc.	$28,000
AstraZeneca Pharmaceuticals LP	$80,000
Bayer AG	$120,000
Bioclinica, Inc.	$10,000
Biogen	$75,600
BrightFocus Foundation	$5,000
C2N Diagnostics	$10,000
Celdara Medical, LLC	$10,000
Celgene Corporation	$40,000
Cognition Therapeutics, Inc.	$10,000
Crohn's and Colitis Foundation	$13,500
Foundation Medicine, Inc.	$15,000
Frederick National Laboratory for Cancer Research	$5,000
Gates Ventures	$15,000
Genmab US, Inc.	$15,000
Gilead Sciences, Inc.	$40,000
Ikena Oncology	$10,000
Invicro, LLC	$10,000
Jazz Pharmaceuticals plc	$50,000
Johnson & Johnson	$150,000
Laboratory Corporation of America	$10,000
Eli Lilly and Company	$300,000
Lundbeck	$30,000
The Multiple Myeloma Research Foundation	$5,000
Nordic Bioscience A/S	$10,000
Novartis Pharmaceuticals Corporation	$40,000
Olink Proteomics	$10,000
PathAI, Inc.	$27,000
Pfizer Inc.	$120,000
Precision Medicine Group	$10,000
ProMIS Neurosciences, Inc.	$10,000
Radiological Society of North America	$5,000
ROCHE	$80,000
Sage Therapeutics	$15,000
Sanofi	$150,000
Sengenics Corporation	$10,000
Sjögren's Foundation, Inc.	$5,000
Society for Immunotherapy of Cancer	$13,500
Takeda Pharmaceutical Company Limited	$405,000
UCB, Inc.	$56,000

BC - Mucosal Healing in Ulcerative Colitis

Boehringer Ingelheim Pharmaceuticals, Inc.	$206,667
Bristol-Myers Squibb	$206,667
Crohn's and Colitis Foundation	$33,334
Johnson & Johnson	$206,666
Eli Lilly and Company	$206,667
Pfizer Inc.	$206,667
Kenneth Rainin Foundation	$200,000
Regeneron Pharmaceuticals, Inc.	$150,000
Takeda Pharmaceutical Company Limited	$206,667

BC - Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration in Familial Frontotemporal degeneration (f-FTD) support NfL

Biogen	$560,000
The Bluefield Project to Cure Frontotemporal Dementia	$107,466

BC - Non-Invasive Biomarkers of Metabolic Liver Disease

Gilead Sciences, Inc.	$350,000
ROCHE	$350,000

BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's Disease

Alzheimer's Drug Discovery Foundation	$201,000

BC - Pre-competitive Analytical Validation of SV2A PET as a Biomarker of Synaptic Density

AbbVie Inc.	$866,729
BrightFocus Foundation	$300,000

BC - PROGRESS OA - Osteoarthritis Biomarkers Qualification

Arthritis Foundation	$200,000
EMD Serono, Inc.	$270,500
Novartis Pharmaceuticals Corporation	$250,000

Deeda Blair Research Initiative Fund for Disorders of the Brain

The JM Foundation	$2,500

Cancer Research Fund

Facebook Donors	$827

Combining Epitope Based Vaccine Design with Informatics-Based Evaluation

Bill & Melinda Gates Foundation	$674,943

Comprehensive Cellular Vaccine Immune Monitoring Consortium

Bill & Melinda Gates Foundation	$6,728,636

Futures Fund

Alexandria Real Estate Equities, Inc.	$100,000

Global collaborative for Coordination of Gene Drive Research and Development

Bill & Melinda Gates Foundation	$2,200,000

Government Appropriations

National Institutes of Health	$1,250,000

Helping to End Addiction Long-term Partnership

National Institutes of Health	$40,694

Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.

Driven To Cure, Inc.	$62,025

Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer

Clovis Oncology, Inc.	$792,831
Eli Lilly and Company	$4,263,819
Merck Sharp & Dohme Corp.	$1,624,832
Pfizer Inc.	$1,764,259

mRNA encoded HIV Env-Gag Virus-like-particle Vaccines

Bill & Melinda Gates Foundation	$1,070,092

Medical Research Scholars Program

American Association for Dental Research	$75,000
Colgate-Palmolive Company	$37,500
Doris Duke Charitable Foundation	$350,000

Music and the Brain

Renée Fleming Foundation	$61,850

National Institute of Neurological Disorders and Stroke CNSF K12 Scholar Awards Program

Congress of Neurological Surgeons Foundation	$200,000

NCTN Data Archive De-Identification Project

Bayer AG	$60,000

Dean R. O'Neill Renal Cell Cancer Research Fund

The Pittsburgh Foundation	$535

Pandemic Response Fund

American Hero Novelty	$2,196
F5 Networks	$200
Facebook Donors	$1,185
Kanter Kallman Foundation	$500
KPMG, LLP	$100,000
Sherry and Alan Leventhal Family Foundation	$25,000
Thomas D. Lookabaugh Foundation	$3,000
Pfizer Foundation Matching Gifts Program	$100
The Procter & Gamble Company	$2,500
Ripple Effect	$6,412
Round Table Group	$500
TSMC North America	$100,000

Partnership for Accelerating Cancer Therapies

AbbVie Inc.	$3,000,000
Amgen Inc.	$3,000,000
Boehringer Ingelheim Pharmaceuticals, Inc.	$3,000,000
Bristol-Myers Squibb	$3,000,000
Celgene Corporation	$3,000,000
Gilead Sciences, Inc.	$3,000,000
GlaxoSmithKline	$3,000,000
Johnson & Johnson	$3,000,000
Novartis Pharmaceuticals Corporation	$3,000,000
Pfizer Inc.	$3,000,000
ROCHE	$3,000,000
Sanofi	$3,000,000

The Partnership to Accelerate Novel TB Regimens

Bill & Melinda Gates Foundation	$533,295

Pew Latin American Fellows Awards

The Pew Charitable Trusts	$23,625

Predevelopment Pediatric Oncology Design Phase

Pharmaceutical Research and Manufacturers of America	$180,000

Edmond J. Safra Family Foundation Futures Fund Initiative

The Edmond J. Safra Philanthropic Foundation	$1,000,000

Edmond J. Safra Family Lodge

Bank of America Matching Gifts Program	$500
National Cancer Institute	$560
Northrop Grumman Corporation	$260

Stephen E. Straus Distinguished Lecture

Charities Aid Foundation	$970
Novartis Pharma AG (Switzerland)	$1,700

Temporarily Restricted

Berger Family Foundation, Inc.	$15,000
Posey-Glickert Foundation	$20,000

Understanding the Mechanisms of Intravenous BCG-Induced Protection Against Tuberculosis in Nonhuman Primates

Bill & Melinda Gates Foundation	$1,499,726

Unrestricted

The Air Products Foundation	$250
Amazon Smile Foundation	$560
American Endowment Foundation	$15,000
American Express Company	$428
America's Charities	$3,776
Apple Inc.	$1,500

Carbon Five	$250
Cerf-Dunbar Fund	$1,000
F5 Networks	$688
Facebook Donors	$4,618
Friends of Cancer Research	$10,000
Global Impact Combined Federal Campaign	$12,385
Hogan Lovells US LLP	$45,000
Hubble Charitable Fund	$300
International Monetary Fund	$651
MasterCard Foundation	$334
Pfizer Foundation Matching Gifts Program	$250
Pfizer Inc.	$2,097
Premier Inc	$500
Ripple Effect	$100
The Edmond J. Safra Philanthropic Foundation	$50,000
Benevolent Society Of Maria SS.ma Addolorata	$500
Suncor Energy	$262
Washington University in St. Louis	$1,000
Wiley Rein LLP	$500
Wolk Family Fund	$2,000
The Richard H. Yearick Foundation	$10,000

Using Biomarkers to Predict TB Treatment Duration

Bill & Melinda Gates Foundation	$2,202,620

Donor and Funding Partner Selection Criteria

The FNIH accepts unrestricted gifts, and gifts for specific programs and purposes, provided that they are not inconsistent with its mission, purposes, and priorities.

The FNIH applies a variety of criteria to aid in determining the appropriateness of a gift or contribution to the organization or its programs, to avoid gifts that would reflect unfavorably on or compromise the integrity of the FNIH or the NIH.

The FNIH does not accept gifts that are:

- in violation of the FNIH's statutory authority or state corporate charter
- too restricted in purpose, or too difficult or burdensome to administer
- intended for purposes outside the mission of the FNIH
- from the tobacco industry, unless given as the result of a court settlement
- would compromise the credibility of the research or other funded activity
- otherwise determined to be inappropriate.

The FNIH does not accept anonymous gifts from corporations.

The FNIH reviews gifts for actual or potential conflicts of interest and, if appropriate, alerts or advises its Board of Directors.

Tab Six

Allocation of NIH Support to the FNIH

FNIH 25

Foundation for the
National Institutes of Health

Allocation of NIH Support to the FNIH

FY 2021

Office Space	$	600,000
Unrecovered Program Salary and Benefits		265,000
Staff Retention and Redeployment*		150,000
New Website		85,000
Operating Costs		150,000
Total	**$**	**1,250,000**

* The FNIH affords equal employment opportunity to all qualified persons regardless of race, sex and other characteristics and this applies to job assignments, training, development and other aspects of employment. During the COVID-19 pandemic, the FNIH retrained and redeployed employees where there were critical needs to avoid layoffs and to further its equal employment opportunity commitments. As a result, there were no pandemic-related staffing cuts.

Tab Seven

Financial Statements and Report of the Independent Auditors

FNIH 25

Foundation for the National Institutes of Health

Foundation for the National Institutes of Health, Inc.

Financial Statements

Years Ended December 31, 2020 and 2019

DHG

Table of Contents

Independent Auditors' Report

Board of Directors
Foundation for the National Institutes of Health, Inc.
North Bethesda, MD

Report on the Financial Statements
We have audited the accompanying financial statements of Foundation for the National Institutes of Health, Inc. (a nonprofit organization), which comprise the statements of financial position as of December 31, 2020 and 2019, and the related statements of activities, functional expenses and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements
Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility
Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America and, for 2020 only, the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

DHG

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Foundation for the National Institutes of Health, Inc. as of December 31, 2020 and 2019, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Other Matters

Report on Supplementary Information

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The accompanying schedule of expenditures of federal awards on page 31, as required by Title 2 U.S. *Code of Federal Regulations* (CFR) Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,* is presented for purposes of additional analysis and is not a required part of the financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the financial statements. The information has been subjected to the auditing procedures applied in the audit of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated, in all material respects, in relation to the financial statements as a whole.

Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we have also issued our report dated May 20, 2021, on our consideration of Foundation for the National Institutes of Health, Inc. 's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering Foundation for the National Institutes of Health, Inc.'s internal control over financial reporting and compliance.

Dixon Hughes Goodman LLP

Richmond, VA
May 20, 2021

Foundation for the National Institutes of Health, Inc.
Statements of Financial Position
December 31, 2020 and 2019

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 62,837,436**	$ 29,756,418
NIH receivable	**500,000**	500,000
Contributions receivable, net, current portion	**21,032,937**	7,811,673
Accrued interest	**175,575**	554,097
Prepaid expenses and other receivables	**2,333,403**	300,636
Total current assets	**86,879,351**	38,922,824
Contributions receivable, net, less current portion	**19,825,974**	3,642,795
Investments	**63,285,583**	91,401,689
Property and equipment, net	**1,948,833**	1,574,395
Total assets	**$ 171,939,741**	$ 135,541,703
LIABILITIES AND NET ASSETS		
Current liabilities:		
Accounts payable and accrued expenses	**$ 7,166,950**	$ 10,145,693
Charitable gift annuity	**125,764**	131,791
Total current liabilities	**7,292,714**	10,277,484
Advance receipts on conditional contributions	**1,331,478**	5,147,362
Deferred lease incentive	**1,538,721**	1,187,019
Deferred rent liability	**572,612**	419,548
Total liabilities	**10,735,525**	17,031,413
Net assets:		
Without donor restrictions:		
Unrestricted, general	**6,216,465**	8,664,974
Board designated	**19,152,000**	12,913,000
Total without donor restrictions	**25,368,465**	21,577,974
With donor restrictions	**135,835,751**	96,932,316
Total net assets	**161,204,216**	118,510,290
Total liabilities and net assets	**$ 171,939,741**	$ 135,541,703

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Activities
Year Ended December 31, 2020

	Without Donor Restrictions	With Donor Restrictions	Total
Revenue, support and other changes:			
Contributions	$ 2,507,887	$ 94,473,375	$ 96,981,262
Grants	40,694	-	40,694
In-kind contributions	600,486	-	600,486
Transfers from NIH	1,250,000	-	1,250,000
Donated services	49,500	-	49,500
Fundraising event	330,000	-	330,000
Investment and interest income, net	2,031,490	758,207	2,789,697
Net assets released from restrictions:			
Satisfaction of indirect cost requirements	4,407,246	(4,407,246)	-
Satisfaction of program restrictions	51,920,901	(51,920,901)	-
Total revenue, support and other changes	63,138,204	38,903,435	102,041,639
Expenses:			
Program services:			
Fellowships and training programs	541,462	-	541,462
Memorials, awards and events	521,016	-	521,016
Capital projects	43,887	-	43,887
Research programs	51,546,218	-	51,546,218
Total program services	52,652,583	-	52,652,583
Supporting services:			
Management and general	6,258,111	-	6,258,111
Fundraising	437,019	-	437,019
Total supporting services	6,695,130	-	6,695,130
Total expenses	59,347,713	-	59,347,713
Change in net assets	3,790,491	38,903,435	42,693,926
Net assets, beginning of year	21,577,974	96,932,316	118,510,290
Net assets, end of year	$ 25,368,465	$ 135,835,751	$ 161,204,216

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Activities
Year Ended December 31, 2019

	Without Donor Restrictions	With Donor Restrictions	Total
Revenue, support and other changes:			
Contributions	$ 528,556	$ 49,298,924	$ 49,827,480
Grants	220,665	-	220,665
In-kind contributions	270,780	-	270,780
Transfers from NIH	500,000	-	500,000
Donated services	50,000	-	50,000
Fundraising event	401,000	-	401,000
Investment and interest income, net	4,003,989	1,193,135	5,197,124
Administrative fee, agency transactions and grants	(50,000)	-	(50,000)
Net assets released from restrictions:			
Satisfaction of indirect cost requirements	4,699,724	(4,699,724)	-
Satisfaction of program restrictions	60,668,032	(60,668,032)	-
Total revenue, support and other changes	71,292,746	(14,875,697)	56,417,049
Expenses:			
Program services:			
Fellowships and training programs	939,134	-	939,134
Memorials, awards and events	575,570	-	575,570
Capital projects	60,340	-	60,340
Research programs	59,558,215	-	59,558,215
Total program services	61,133,259	-	61,133,259
Supporting services:			
Management and general	6,123,632	-	6,123,632
Fundraising	552,675	-	552,675
Total supporting services	6,676,307	-	6,676,307
Total expenses	67,809,566	-	67,809,566
Change in donor designation	27,404	(27,404)	-
Change in net assets	3,510,584	(14,903,101)	(11,392,517)
Net assets, beginning of year	18,067,390	111,835,417	129,902,807
Net assets, end of year	$ 21,577,974	$ 96,932,316	$ 118,510,290

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Functional Expenses
Year Ended December 31, 2020

	Program Services					Supporting Services			
	Fellowships and Training Programs	Memorials, Awards and Events	Capital Projects	Research Programs	Total Program Services	Management and General	Fundraising	Total Supporting Services	Total
Salaries and benefits	$ 56,216	$ 84,797	$ 13,450	$ 6,613,708	$ 6,768,171	$ 4,087,391	$ 269,855	$ 4,357,246	$ 11,125,417
Stipends	-	103,500	10,000	355,000	468,500	-	50,000	50,000	518,500
Programs contracts	431,944	326,552	-	32,168,308	32,926,804	-	-	-	32,926,804
Grant awards	-	-	-	8,056,317	8,056,317	-	-	-	8,056,317
Meetings and travel	38,133	3,187	16,051	216,241	273,612	12,140	2,672	14,812	288,424
Office supplies and expense	8,958	207	479	-	9,644	8,175	30	8,205	17,849
Telephone	-	-	-	92,726	92,726	96,517	8,028	104,545	197,271
Books and supplies	344	-	-	10,695	11,039	4,320	-	4,320	15,359
Tuition	-	-	-	-	-	3,645	-	3,645	3,645
Insurance	-	-	-	120,114	120,114	72,499	-	72,499	192,613
Consultants	-	-	-	3,441,965	3,441,965	421,323	38,633	459,956	3,901,921
Professional fees	30	1,950	-	137,511	139,491	161,080	-	161,080	300,571
Depreciation and amortization	-	-	-	-	-	250,896	-	250,896	250,896
Rent/housing	3,534	-	-	176,478	180,012	569,848	-	569,848	749,860
Recruiting	-	-	-	5,565	5,565	5,279	-	5,279	10,844
Relocation	-	-	-	-	-	339,228	-	339,228	339,228
Dues and subscriptions	-	-	-	11,507	11,507	11,591	-	11,591	23,098
Equipment and rental and maintenance	1,380	-	-	4,387	5,767	45,783	-	45,783	51,550
Printing and photocopying	-	-	-	20,238	20,238	9,804	40,835	50,639	70,877
Postage and delivery	14	163	66	31,678	31,921	3,092	5,879	8,971	40,892
Service charges	435	170	240	4,886	5,731	18,790	590	19,380	25,111
Communication	474	490	-	64,712	65,676	105,209	20,497	125,706	191,382
Advertising and promotion	-	-	-	13,944	13,944	10,084	-	10,084	24,028
Miscellaneous	-	-	3,601	238	3,839	21,417	-	21,417	25,256
	$ 541,462	$ 521,016	$ 43,887	$ 51,546,218	$ 52,652,583	$ 6,258,111	$ 437,019	$ 6,695,130	$ 59,347,713

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Functional Expenses
Year Ended December 31, 2019

	Program Services					Supporting Services			
	Fellowships and Training Programs	Memorials, Awards and Events	Capital Projects	Research Programs	Total Program Services	Management and General	Fundraising	Total Supporting Services	Total
Salaries and benefits	$ 48,372	$ 62,963	$ 13,655	$ 5,588,107	$ 5,713,097	$ 4,074,426	$ 287,798	$ 4,362,224	$ 10,075,321
Stipends	500	111,434	10,000	15,000	136,934	-	-	-	136,934
Programs contracts	769,001	311,109	-	38,977,021	40,057,131	-	-	-	40,057,131
Grant awards	-	-	-	10,519,901	10,519,901	-	-	-	10,519,901
Meetings and travel	93,713	83,422	31,275	2,165,189	2,373,599	76,849	113,135	189,984	2,563,583
Office supplies and expense	2,834	488	1,461	-	4,783	14,902	1,038	15,940	20,723
Telephone	-	-	-	84,140	84,140	95,576	7,776	103,352	187,492
Books and supplies	833	-	1,306	26,077	28,216	8,132	1,192	9,324	37,540
Tuition	-	-	-	3,633	3,633	2,975	-	2,975	6,608
Insurance	-	-	-	101,082	101,082	71,796	-	71,796	172,878
Consultants	-	-	600	1,369,460	1,370,060	289,770	49,910	339,680	1,709,740
Professional fees	1,950	-	-	192,707	194,657	145,940	-	145,940	340,597
Depreciation and amortization	-	-	-	-	-	189,073	-	189,073	189,073
Rent/housing	3,120	-	-	128,877	131,997	432,957	-	432,957	564,954
Recruiting	-	-	-	53,836	53,836	33,471	-	33,471	87,307
Relocation	-	-	-	-	-	398,679	-	398,679	398,679
Temporary services	-	-	-	2,640	2,640	240	-	240	2,880
Dues and subscriptions	-	-	-	18,390	18,390	14,854	-	14,854	33,244
Equipment and rental and maintenance	16,878	-	-	5,939	22,817	40,072	-	40,072	62,889
Printing and photocopying	-	1,385	-	93,562	94,947	48,973	49,088	98,061	193,008
Postage and delivery	-	136	-	115,125	115,261	2,963	3,895	6,858	122,119
Service charges	1,329	1,116	227	6,473	9,145	23,062	1,953	25,015	34,160
Communication	14	3,242	-	76,640	79,896	148,226	30,481	178,707	258,603
Advertising and promotion	-	-	-	14,026	14,026	8,302	2,125	10,427	24,453
Miscellaneous	590	275	1,816	390	3,071	2,394	4,284	6,678	9,749
	$ 939,134	$ 575,570	$ 60,340	$ 59,558,215	$ 61,133,259	$ 6,123,632	$ 552,675	$ 6,676,307	$ 67,809,566

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statements of Cash Flows
Years Ended December 31, 2020 and 2019

	2020	2019
Cash flows from operating activities:		
Change in net assets	**$ 42,693,926**	$ (11,392,517)
Adjustments to reconcile change in net assets to net cash provided (used) by operating activities:		
Depreciation and amortization	**250,896**	189,073
Contributions restricted for long-term purposes	**(511,998)**	(259,681)
Net realized and unrealized gain on investments	**(1,238,818)**	(2,558,778)
Deferred lease incentive amortization	**(130,033)**	(92,495)
Deferred rent liability	**153,064**	35,771
Change in assets and liabilities:		
Contributions receivable	**(29,404,443)**	5,816,079
NIH receivable	**-**	(500,000)
Accrued interest	**378,522**	(88,263)
Prepaid expenses and other receivables	**(2,032,767)**	(50,882)
Accounts payable and accrued expenses	**(2,978,743)**	6,260,921
Funds held for others, agency transactions	**-**	(1,235,000)
Charitable gift annuity	**(6,027)**	(6,146)
Advance receipts on grants	**-**	(2,870,167)
Advance receipts on conditional contributions	**(3,815,884)**	1,947,362
Net cash provided (used) by operating activities	**3,357,695**	(4,804,723)
Cash flows from investing activities:		
Furniture and equipment acquisitions	**(143,599)**	(210,044)
Sales and maturities of investments	**115,312,812**	98,377,402
Purchase of investments	**(85,957,888)**	(84,434,637)
Net cash provided by investing activities	**29,211,325**	13,732,721
Cash flows from financing activities:		
Contributions restricted for investment in endowment	**511,998**	259,681
Net increase in cash and cash equivalents	**33,081,018**	9,187,679
Cash and cash equivalents, beginning of year	**29,756,418**	20,568,739
Cash and cash equivalents, end of year	**$ 62,837,436**	$ 29,756,418
Supplemental disclosure of noncash transactions:		
Leasehold improvements acquired with lease incentive	**$ 481,735**	$ -

See accompanying notes.

Notes to Financial Statements

1. Organization and Nature of Activities

Foundation for the National Institutes of Health, Inc. (Foundation) is a not-for-profit organization, whose mission is to create and lead alliances and public-private partnerships that advance breakthrough biomedical discoveries and improve the quality of people's lives.

2. Summary of Significant Accounting Policies

Basis of accounting

The financial statements of the Foundation have been prepared on the accrual basis of accounting and, accordingly, reflect all significant receivables, payables, and other liabilities.

Basis of presentation

The Foundation reports information regarding its financial position and activities according to two classes of net assets: without donor restrictions and with donor restrictions.

- Net assets without donor restrictions – not subject to donor-imposed restrictions and may be expended for any purpose in performing the primary objectives of the organization. These net assets may be used at the discretion of the Foundation's management and the board of directors.
- Net assets with donor restrictions – subject to stipulations imposed by donors, and grantors. Some donor restrictions are temporary in nature; those restrictions will be met by actions of the Foundation or by the passage of time. Other donor restrictions are perpetual in nature, whereby the donor has stipulated the funds be maintained in perpetuity.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Cash and cash equivalents

For purposes of the financial statement presentation, cash and cash equivalents includes all cash on hand, demand accounts, and highly-liquid investments with original maturities of three months or less, excluding temporarily uninvested money market funds held in brokerage accounts.

Investments

Investments are reported at market value. Realized gains or losses are recognized upon sale or disposal. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date. Unrealized gains and losses, due to market fluctuations during the year, are recognized at year-end.

Contributions and other receivables

Unconditional contributions receivable that are expected to be collected within one year are recorded at net realizable value. Unconditional contributions to be collected in more than one year are recorded at net present value, which approximates fair value. Conditional contributions receivable are recognized when the conditions on which they depend are substantially met. Credit risk for contributions receivable is concentrated, as a significant amount of contributions receivable are received from a few donor organizations. Other receivables are stated at net realizable value and are deemed fully collectible by management.

Allowance for uncollectible receivables

Contributions receivable are stated at unpaid balances, less an allowance for doubtful accounts. Management has established an allowance for uncollectible contributions receivable based on a review of historical collections. Receivables are considered delinquent if full principal payments are not received in accordance with the contractual terms. It is the Foundation's policy to charge off uncollectible accounts receivable when management determines the receivable will not be collected. Amounts recorded as other receivables are deemed to be fully collectible by management. Accordingly, an allowance has not been recorded for those receivables.

Property and equipment

Property and equipment purchases are recorded at cost. Depreciation is computed using the straight-line method based on the following estimated useful lives:

Furniture and equipment	3 - 5 years
Leasehold improvements	15 years

The Foundation's policy is to capitalize furniture and equipment purchased with a cost of $1,000 or more. Donated equipment is recorded at fair value at the date of contribution.

Deferred rent and incentives

Deferred rent is recorded and amortized to the extent the total minimum rental payments allocated to the current period on a straight-line basis exceed or are less than the cash payments required. Deferred leasehold incentives are recorded and amortized over the life of the lease.

Contributions

Contributions received are recorded as net assets without donor restrictions or net assets with donor restrictions, depending on the existence and/or nature of any donor-imposed restrictions. When a restriction expires (that is, when a stipulated time restriction ends or purpose restriction is accomplished), net assets with donor restrictions are reclassified to net assets without donor restrictions and reported in the statements of activities as net assets released from restrictions. Grants and contributions considered to be nonexchange transactions that include donor-imposed conditions are recognized as revenue when the condition is met. Funds received by the Foundation for conditional contributions are recorded as a liability until the conditions are met.

Grant revenues

Amounts received under grant awards are considered exchange transactions and are recognized as unrestricted revenue when the related expenses are incurred. Unexpended amounts received are recorded as deferred grant revenue. Expenditures in excess of receipts are recorded as grants receivable.

Agency transactions

The Foundation recognizes a liability equal to the fair value of assets received by the Foundation for which the donor stipulates that the assets are to be used on behalf of the donor or another entity (the beneficiary) or to be transferred to another entity.

Transfers from NIH revenue recognition

Transfers from NIH are recognized as revenue in the year they are approved.

Fundraising event revenue recognition

Amounts received to attend the annual award ceremony are considered exchange transactions as a reciprocal benefit is received by the attendees. The revenues associated with this event are recognized at a point in time, on the date of the event, at which time the Foundation's performance obligation is satisfied. There are no elements of variable consideration, contract costs, or significant financing components associated with this revenue.

Functional expenses

The costs of providing program and other activities have been summarized on a functional basis in the financial statements. Accordingly, certain costs have been allocated among program services and supporting services benefited. Such allocations are determined by management on an equitable basis.

The expenses that are allocated include the following:

Expense	Method of Allocation
Salaries and benefits	Time and effort
Stipends	Time and effort
Program contracts	Time and effort
Grant awards	Time and effort
Meetings and travel	Time and effort
Office supplies and expense	Time and effort
Telephone	Headcount/Time and effort
Books and supplies	Headcount/Time and effort
Tuition	Time and effort
Insurance	Headcount
Consultants	Time and effort
Professional fees	Time and effort
Depreciation	Time and effort
Rent and housing	Square footage
Recruiting	Time and effort
Relocation	Time and effort
Temporary services	Time and effort
Dues and subscriptions	Time and effort
Equipment and rental	Headcount/Time and effort
Printing and photocopying	Time and effort
Postage and delivery	Time and effort
Service charges	Time and effort
Communications	Time and effort
Advertising and promotion	Time and effort
Miscellaneous	Time and effort

Income taxes

The Foundation is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code; accordingly, the accompanying financial statements do not reflect a provision or liability for federal and state income taxes. The Foundation has determined that it does not have any material unrecognized tax benefits or obligations as of December 31, 2020 and 2019.

Recently issued accounting standards

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases*. Under the new standards, lessees will need to recognize a right-of-use asset and a lease liability for virtually all their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. For statement of activity purposes, the FASB continued the dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied to current lease accounting. Extensive quantitative and qualitative disclosures will be required to provide greater insight into the extent of revenue and expense recognized and expected to be recognized from existing contracts. The new standard will be effective for the Foundation on January 1, 2022, and the Foundation is currently evaluating the effect this accounting standard may have on its financial statements.

Subsequent events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 20, 2021, the date the financial statements were available to be issued.

3. Availability and Liquidity

The following represents the Foundation's financial assets at December 31:

	2020	2019
Financial assets:		
Cash and cash equivalents	**$ 62,837,436**	$ 29,756,418
NIH receivable	**500,000**	500,000
Contributions receivable, net	**40,858,911**	11,454,468
Other receivables	**2,097,652**	52,378
Investments	**63,285,583**	91,401,689
Total financial assets	**169,579,582**	133,164,953

Less amounts not to be used within one year:		
Net assets with donor restrictions	**135,835,751**	96,932,316
Legacy Fund established by the board	**1,601,000**	1,601,000
Quasi endowment established by the board	**15,549,000**	10,412,000
	152,987,751	108,945,316
Financial assets available to meet general expenditures over the next twelve months	**$ 16,591,831**	$ 24,219,637

The Foundation's goal is to maintain financial assets to meet one year of Supporting Services (approximately $8.2 million). As part of its liquidity plan, excess cash is invested in short-term investments, including money market accounts and high-quality fixed income securities with a maximum maturity of 3 years.

4. Concentration of Credit Risk

Financial instruments that potentially subject the Foundation to concentration of credit risk consist of cash transaction accounts. The Foundation places its cash transaction accounts with high credit quality financial institutions. At December 31, 2020 and 2019, the Foundation had deposits in excess of the amount insured by the Federal Deposit Insurance Corporation (FDIC). The Foundation has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk on cash and cash equivalents.

5. Property and Equipment

Major classes of property and equipment consisted of the following:

	2020	**2019**
Furniture and equipment	**$ 1,079,148**	$ 935,548
Leasehold improvements	**1,869,159**	1,387,425
	2,948,307	2,322,973
Accumulated depreciation and amortization	**(999,474)**	(748,578)
	$ 1,948,833	$ 1,574,395

6. Investments

Investments as of December 31, 2020, are summarized as follows:

	Cost	Market Value
Money market funds	**$ 3,649,303**	**$ 3,649,303**
U.S. government bonds	**41,735,670**	**41,959,728**
Exchange traded funds	**2,086,390**	**2,355,265**
Mutual funds	**12,891,380**	**15,321,287**
	$ 60,362,743	**$ 63,285,583**

The following schedule summarizes the investment return and its classification for 2020:

	Without Donor Restrictions	With Donor Restrictions	Total
Interest and dividends	**$ 1,386,150**	**$ 336,807**	**$ 1,722,957**
Realized gain	**64,135**	**6,223**	**70,358**
Unrealized gain	**753,283**	**415,177**	**1,168,460**
Investment fees	**(172,078)**	**-**	**(172,078)**
Total investment return	**$ 2,031,490**	**$ 758,207**	**$ 2,789,697**

Investments as of December 31, 2019, are summarized as follows:

	Cost	Market Value
Money market funds	$ 3,254,540	$ 3,254,540
U.S. government bonds	71,883,010	72,119,707
Exchange traded funds	1,774,338	1,947,293
Mutual funds	12,793,415	14,080,149
	$ 89,705,303	$ 91,401,689

The following schedule summarizes the investment return and its classification for 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Interest and dividends	$ 2,382,347	$ 435,987	$ 2,818,334
Realized gain (loss)	345,963	(385)	345,578
Unrealized gain	1,455,667	757,533	2,213,200
Investment fees	(179,988)	-	(179,988)
Total investment return	$ 4,003,989	$ 1,193,135	$ 5,197,124

7. Contributions Receivable

Contributions receivable at December 31, were as follows:

	2020	2019
Receivable in less than one year	**$ 21,047,937**	$ 7,826,673
Receivable in one to five years	**20,272,058**	3,746,667
Total unconditional contributions receivable	**41,319,995**	11,573,340
Discounts to net present value	**(446,084)**	(103,872)
Allowance for uncollectible contributions receivable	**(15,000)**	(15,000)
Net unconditional contributions receivable	**$ 40,858,911**	$ 11,454,468

The discount rate used on long-term contributions receivable was 2.25% in 2020 and 2019.

8. Conditional Contributions Receivable

As of December 31, the Foundation had the following contributions receivable subject to donor conditions:

	2020	2019
Conditioned upon the funder not notifying the Foundation by a specific date that they do not wish to fund the program:		
Comprehensive Cellular Vaccine Immune Monitoring Consortium	**$ -**	$ 766,745
Using Biomarkers to Predict TB Treatment Duration	**956,860**	3,159,480
Lurie Prize in Biomedical Research	**100,000**	200,000
Pew Latin American Fellows Awards	**296,625**	183,750
Efficacy of Heterodimeric IL-15 Treatment Regimens in Reducing SIV Reservoir	**765,405**	765,405
Conditioned upon meeting certain milestones and/or the funder not cancelling:		
NIH Medical Research Scholars Program	**150,000**	180,000
Alzheimer's Disease Neuroimaging Initiative-3	**228,332**	2,511,683
Biomarkers Consortium Treatments Against Rheumatoid Arthritis and Effect on FDG PET-CT	**60,000**	60,000
Amgen NIH Scholars Program	**335,000**	335,000
Pamela Anne Cafritz Renal Cell Carcinoma Award	**100,000**	200,000
Biomarkers Consortium Osteoarthritis Biomarkers Qualification	**700,000**	1,041,000
Biomarkers Consortium Inflammatory Markers for Neurodegenerative and Mood Disorders	**554,500**	477,000
Partnership for Accelerating Cancer Therapies	**-**	36,000,000
NCTN Data Archive De-Identification Project	**-**	60,000
Biomarkers Consortium ctDNA Reference Standards	**490,271**	980,542
Chemotherapeutic Impact on the Immune MicroEnvironment Project (ChIIME)	**1,250,000**	1,250,000
Participation of Native American Students in the National Institute for Neurological Disorders and Stroke (NINDS)	**60,000**	60,000
Non-Invasive BioMarkers of MetaBolic Liver DiseasE (NIMBLE) (Project is not yet launched)	**5,845,888**	6,545,888

Understanding NHP protection against TB induced by Intravenous BCG	**2,399,613**	916,656
LungMap	**-**	1,576,862
CAR-T	**556,251**	1,318,544
ADNI – Amyloid PET Early Frames Add on Study	**50,000**	100,000
Biomarkers Consortium – Plasma Abeta project	**1,201,717**	1,000,717
2019 NINDS/CNS Getch Scholar	**100,000**	300,000
iUFV (Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine)	**-**	674,943
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**3,499,008**	3,499,008
Mucosal Healing in Ulcerative Colitis	**3,436,665**	420,000
GeneConvene Global Collaborative	**15,564,694**	17,764,694
Accelerating Medicines Partnership – Schizophrenia	**3,600,000**	-
NIP- Metastatic Prostate Cancer	**200,000**	-
BC-Cachexia	**950,000**	-
Joram Piatigorsky Basic Science Lecture and Award	**600,000**	-
Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration	**32,534**	-
The Partnership to Accelerate Novel TB Regimens (PAN-TB)	**737,580**	-
Accelerating Medicines Partnership – Alzheimer's Disease 2.0 (AMP-AD 2.0)	**3,228,000**	-
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines (mRNA VLPs)	**389,908**	-
Accelerating Medicines Partnership: AIM	**400,000**	-
	$ 48,838,851	$ 82,347,917

Since these represent conditional contributions receivable, they are not recorded as contributions receivable and contribution revenue until donor conditions are met.

9. Board Designated Net Assets

The Board of Directors has established three board designated funds as follows at December 31:

	2020	**2019**
Endowment Fund	**$ 15,549,000**	$ 10,412,000
Contingency Fund	**2,000,000**	900,000
Legacy Fund	**1,601,000**	1,601,000
	$ 19,152,000	$ 12,913,000

10. Net Assets with Donor Restrictions

As of December 31, net assets with donor restrictions were available for the following purposes:

	2020	2019
Fellowships and Training Programs:		
Amgen Scholars Program	**$ 150,177**	$ 150,177
Dean R. O'Neill Renal Cell Cancer Research Fund	**192,370**	181,482
Dr. Edward T. Rancic Memorial Fund	**6,705**	6,648
Dr. John L. Barr Memorial Fund for Cancer Research	**686**	686
Neva Fund	**28,388**	28,144
NIH Medical Research Scholarship Program	**1,041,159**	1,007,706
NOB Fund	**7,152**	7,152
Norman P. Salzman Memorial Award and Lecture in Virology	**234,886**	231,690
Notkins biomedical Research Fund	**201,737**	200,000
Robert Whitney Newcomb Memorial Lecture and Internship	**1,422,112**	1,288,012
Sallie Rosen Kaplan Fellowship for Women Scientists in Cancer Research	**254,328**	185,984
Swanson Family Fellowship in Generic Thyroid Benign Chorea and IgA Deficiency (TTF-1)	**92,500**	92,500
Memorials, Awards and Events:		
2017 AD Caregiving Summit	**-**	44,717
Adam J. Berry Memorial Fund	**8,146**	6,770
Breast Cancer Summit 2	**65,198**	65,198
Carcinoid Summit Workshop	**-**	17,594
Celebrating 50 Years of Brain Research: New Discoveries, New Hope	**171,451**	171,451
Dr. Anita Roberts Memorial Fund	**24,150**	24,150
Dr. Jane M. Sayer Vision Research Lecture and Award	**274,883**	272,169
Edna Williams Curl & Myron R. Curl Endowment for Multiple Sclerosis Research	**67,370**	66,790
Human Genome Exhibition	**9,245**	9,325
John Laws Decker Memorial Fund	**2,346**	2,325
Joram Piatigorsky Basic Science Lecture and Award	**401,380**	-
Kovler Prize for Excellence in Science Journalism	**300,507**	198,781
Lurie Prize	**100,000**	100,000
MRSP 2019-2020	**-**	205,040
MRSP 2020-2021	**156,283**	-
Michael T. Davis Fund	**73,072**	-
NINDS/CNSF K12 Scholar Awards Program	**195,000**	-
Pamela Ana Cafritz	**100,000**	196,960
Pandemic Response Fund	**292,107**	-
Polio Conference	**-**	40,698
Stephen E. Straus Award	**104,903**	100,489
Capital Projects:		
Edmond J. Safra Family Lodge Bricks and Mortar	**79,759**	79,759
Edmond J. Safra Family Lodge All Programs	**39,692**	24,212
Edmond J. Safra Family Lodge GSK Endowment	**538,000**	371,673
Edmond J. Safra Family Lodge Weinberg Endowment	**351,512**	259,391
Edmond J. Safra Family Lodge Gallin Endowment	**111,252**	109,188
Tracy's Toy Box	**7,941**	7,941
Research Partnerships:		
Accelerating Medicines Partnership Membership	**460,029**	565,930
Accelerating Medicines Partnership: Type 2 Diabetes	**3,046,060**	8,006,894
Accelerating Medicines Partnership: Alzheimer's	**2,504,340**	4,159,605
Accelerating Medicines Partnership: Alzheimer's Disease 2.0	**7,943,051**	-
Accelerating Medicines Partnership: AIM	**100,000**	-
Accelerating Medicines Partnership: Rheumatoid Arthritis and Lupus	**1,096,038**	4,254,460
Accelerating Medicines Partnership: Parkinson’s Disease	**7,604,247**	9,915,954

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Accelerating Medicines Partnership: Schizophrenia	**5,223,326**	-
Accelerating Medicines Partnership: Common Metabolic Diseases (AMP CMD)	**1,681,296**	-
ADNI - Amyloid PET Early Frames Add on Study	**677,500**	652,500
ADNI - Optimization of Alzheimer's Disease Cognitive Measures Project	**-**	15,980
Alzheimer's Disease Neuroimaging Initiative – 3	**2,715,451**	3,509,396
AMP - Heart Failure- Design Phase	**244,315**	-
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**65,134**	1,209,047
Biomarker Consortium	**3,935,197**	3,055,502
Biomarkers Consortium: Atherosclerosis Computer Modeling	**358,639**	366,852
Biomarkers Consortium: Autism Spectrum Disorder	**-**	70,426
Biomarkers Consortium: Bone Quality Project	**22,320**	46,221
Biomarkers Consortium: CABP-Skin Infection	**19,263**	19,736
Biomarkers Consortium: HABP/VABP Working Group	**-**	3,747
Biomarkers Consortium: HD-SCA in CRC (High Definition Single Cell Analysis of Blood and Tissue Biopsies	**32,389**	37,895
Biomarkers Consortium: Inflammatory Markers for Neurodegenerative and Mood Disorders	**683,943**	364,482
Biomarkers Consortium: Kidney Safety	**-**	32,971
Biomarkers Consortium: Longitudinal CSF Proteomics	**11,306**	92,704
Biomarkers Consortium: MRD Project	**819,021**	1,065,511
Biomarkers Consortium: Novel Cardiac Biomarkers in the General US Population	**116,732**	181,670
Biomarkers Consortium: OA BMxQ	**1,231,958**	1,174,758
Biomarkers Consortium: Target BMx	**82,526**	308,375
Biomarkers Consortium: Vol-PACT	**269,199**	421,623
Biomarkers Consortium: PACT Implementation	**42,959,963**	13,331,809
BC – Cachexia	**350,000**	-
Bradley Charitable Gift Annuity	**10,240**	17,518
Cancer Research Fund	**1,443,911**	1,432,348
Cancer Research Major Gift	**4,587,225**	4,737,225
Charles A. Sanders Legacy Fund	**1,144,209**	1,352,218
Chemotherapeutic Impact on the Immune MicroEnvironment	**81,204**	89,618
Comprehensive Cellular Vaccine Immune Monitoring Consortium (CVIMC)	**6,875,918**	2,713,591
Consensus Pathway for Gene Drive in Mosquitoes	**186,570**	187,673
ctDNA Reference Standards	**877,809**	561,721
Developing Evidence-Based Music Therapies	**61,850**	-
Deeda Blair Research Initiative Fund for Disorders of the Brain	**198,018**	387,361
Essential Strategies to Combat Ebola in West Africa: Social Mobilization and Communications	**-**	652
Eliminate Dengue	**-**	3,320
Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D	**148,212**	148,212
FNIH Travel support for NIH Scientists	**404,330**	412,816
Follicular Lymphoma Research Fund	**7,650**	2,700
GeneConvene Global Collaborative	**4,095,702**	5,305,808
Gilead HIV Cure Grants	**1,414,971**	1,890,104
Gramlich Melanoma Research Trust	**200,751**	200,751
iUFV (Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine)	**441,240**	1,061,655
Kidney Cancer Research	**67,515**	106,042
Lung Cancer Master Protocol (LungMAP)	**2,314,428**	1,615,637
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines	**677,981**	-
Mucosal Healing in Ulcerative Colitis	**1,823,335**	200,000
Multiple Myeloma Accumulation Rate (MAR)	**-**	136,000
Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration	**664,602**	-
NCTN Data Archive De-Identification Project	**133,931**	79,671
Non-Invasive Biomarkers of Metabolic Liver Disease	**5,959,610**	6,117,104

NIP- Metastatic Prostate Cancer	**48,646**	-
OPIOIDS Stakeholder	**100,000**	100,000
Partnership for Accelerating Cancer Therapies	**-**	3,693
Partnership to Accelerate Novel TB Regimens (PAN-TB)	**527,210**	-
Plasma Abeta Project	**1,056,220**	1,000,717
PREDICT-TB	**876,312**	763,866
Rapid identification of individuals with viable adult female worms of Onchocerca volvulus: a means to the end	**-**	81
Risk Assessment GeneConvene Interest	**1,991,619**	-
SHORTEN-TB	**79,873**	100,261
Solarz Memorial Fund	**40,204**	19,276
Spiromic Project	**-**	3,396
Structure-Based Vaccine D	**11,167**	26,575
Support functions for VCTR	**-**	1,969,908
SV2A PET Tracer as a Biomarker for Synaptic Density	**1,150,447**	-
The Lowy Cancer Research Support Fund	**3,812**	3,812
Transitional Support Gene Drive Research	**-**	1,683,282
Tuberculosis Vaccine	**220,022**	81,821
Other Temporarily Restricted Programs	**613,217**	369,182
Total Temporarily Restricted Net Assets	**131,899,601**	93,504,465
Perpetual Endowments:		
Edmond J. Safra Family Lodge:		
GlaxoSmithKline Endowment Fund	**1,500,000**	1,500,000
Harry and Jeanette Weinberg Endowment at the Edmond J. Safra Family Lodge	**830,894**	830,894
Sallie Rosen Kaplan Fellowship for Women Scientists in Cancer Research	**707,771**	707,771
CarMollNat Muscular Dystrophy Endowment	**49,853**	39,186
Futures Fund	**847,632**	350,000
Total Perpetual Endowments	**3,936,150**	3,427,851
	$ 135,835,751	$ 96,932,316

11. Endowments

The Foundation's endowments consist of individual donor-restricted endowment funds established for a variety of purposes and board designated endowments. Net assets associated with endowment funds are classified and reported based on the existence or absence of donor-imposed restrictions.

Interpretation of relevant law

The Board of Directors of the Foundation has interpreted the Maryland State Prudent Management of Institutional Funds Act (SPMIFA) as requiring the preservation of the fair value of the original gift as of the gift date of the donor-restricted endowment funds absent explicit donor stipulations to the contrary. As a result of the interpretation, the Foundation retains in perpetuity (a) the original value of the gifts donated to the permanent endowment, (b) the original value of subsequent gifts to the permanent endowment, and (c) accumulations to the permanent endowment made in accordance with the direction of the applicable donor gift instrument at the time of the accumulation to the fund. Donor-restricted amounts not retained in perpetuity are subject to appropriation for expenditures by the Foundation in a manner consistent with the standard of prudence prescribed by SPMIFA. The Foundation considers the following factors in making a determination to appropriate or accumulate donor-restricted endowment funds:

1. The duration and preservation of the fund
2. The purposes of the Foundation and the donor-restricted endowment fund
3. General economic conditions
4. The possible effect of inflation and deflation
5. The expected total return from income and the appreciation of investments
6. Other resources of the Foundation
7. The investment policies of the Foundation

The endowment net asset composition, by type of fund, was as follows as of December 31, 2020:

	Without Donor Restrictions	With Donor Restrictions	Total
Board-designated endowment funds	**$ 15,549,000**	**$ -**	**$ 15,549,000**
Donor-restricted endowment funds:			
Original donor-restricted gift amount and amounts required to be maintained in perpetuity by donor	**-**	**3,936,150**	**3,936,150**
Accumulated investment gains	**-**	**1,392,885**	**1,392,885**
Total endowment funds	**$ 15,549,000**	**$ 5,329,035**	**$ 20,878,035**

The changes in endowment assets were as follows for 2020:

	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, beginning of year	**$ 10,412,000**	**$ 4,485,505**	**$ 14,897,505**
Investment return:			
Investment income	**-**	**135,663**	**135,663**
Net appreciation (realized and unrealized)	**-**	**284,319**	**284,319**
Total investment return	**-**	**419,982**	**419,982**
Contributions	**-**	**511,998**	**511,998**
Additional board designation	**5,137,000**	**-**	**5,137,000**
Appropriation of endowment assets for expenditure	**-**	**(88,450)**	**(88,450)**
Endowment net assets, end of year	**$ 15,549,000**	**$ 5,329,035**	**$ 20,878,035**

The endowment net asset composition, by type of fund, was as follows as of December 31, 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Board-designated endowment funds	$ 10,412,000	$ -	$ 10,412,000
Donor-restricted endowment funds:			
Original donor-restricted gift amount and amounts required to be maintained in perpetuity by donor	-	3,427,851	3,427,851
Accumulated investment gains	-	1,057,654	1,057,654
Total endowment funds	$ 10,412,000	$ 4,485,505	$ 14,897,505

The changes in endowment assets were as follows for 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, beginning of year	$ 8,887,000	$ 3,627,811	$ 12,514,811
Investment return:			
Investment income	-	129,593	129,593
Net appreciation (realized and unrealized)	-	576,307	576,307
Total investment return	-	705,900	705,900
Contributions	-	263,682	263,682
Additional board designation	1,525,000	-	1,525,000
Appropriation of endowment assets for expenditure	-	(111,888)	(111,888)
Endowment net assets, end of year	$ 10,412,000	$ 4,485,505	$ 14,897,505

Return objectives and risk parameters

The Foundation has adopted investment and spending policies for endowment assets that attempt to maximize long-term results, consistent with a prudent level of risk while seeking to maintain the purchasing power of the endowment assets. Endowment assets include those assets of donor-restricted funds that the Foundation must hold in perpetuity or for a donor-specified period or purpose. Under this policy, as approved by the Board of Directors, the endowment assets are invested to maximize long-term results, consistent with a prudent level of risk. The goal is to produce a return on the assets to support the programmatic purposes, while also achieving growth of principal in order to maintain real purchasing power. This approach helps assure that gifts to endowment funds keep pace with inflation and always support the designated activity.

Strategies employed for achieving objectives

To satisfy its long-term rate-of-return objectives, the Foundation relies on a total return strategy in which the investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). The Foundation targets a diversified asset allocation that balances fixed-income and equity-based investments to achieve its long-term return objectives within prudent risk constraints.

12. Grant Revenue

The Foundation receives a portion of its support under certain grants and contributions that may be audited by the donors and the ultimate determination of allowable costs is determined by such audits.

13. In-Kind Contributions

Telephone expense, on-line communication costs, and some office space for the Foundation are donated by NIH. The value of the telephone expense, value of the on-line communication costs, and estimated rental value of the office space, has been reflected in the accompanying financial statements as in-kind contributions with a like amount recorded as telephone expense, communications expense, program expenses or rent/housing expense. For 2020 and 2019, these in-kind contributions from NIH of $278,004 and $270,780, respectively, are reflected in the financial statements.

During 2020, additional in-kind contributions of $322,482 were received from various donors for meeting expenses and use in program activities.

14. Donated Services

The Foundation receives benefit from services donated by NIH, which include various administrative and technical services performed by NIH employees. The estimated value of these services is based on the hourly rate and average benefit amount of the NIH employees. The estimated amount of these services has been reflected in the accompanying financial statements as donated services with a like amount recorded as salaries and benefits expense.

The Foundation also receives benefit from donated legal services. The value of these services has been reflected in the financial statements as donated services with a like amount recorded as professional fees expense.

For 2020 and 2019, donated services of $49,500 and $50,000, respectively, are reflected in the financial statements.

15. Retirement Plan

The Foundation has a retirement plan through TIAA-CREF. The plan calls for a mandatory contribution of at least 2% of annual salary from participating employees and an additional contribution of 10% of annual salary from the Foundation. Retirement plan expense for 2020 and 2019 was $844,686 and $762,039, respectively.

16. Concentration of Revenue

For 2020 and 2019, the Foundation received approximately 15% and 35%, respectively, of its revenue from contributions and grants from the Bill and Melinda Gates Foundation.

17. Relationship with the Foundation for Advanced Education in the Sciences, Inc.

The Foundation was established under legislation that authorized it to be the sole entity responsible for soliciting funds on behalf of NIH and to conduct specific other activities that support NIH in its mission. Certain of the activities described in the legislation are conducted by the Foundation for Advanced Education in the Sciences, Inc. (FAES) under a Memorandum of Understanding (MOU) with the Foundation. This MOU preserves the prerogatives conferred on the Foundation by its authorizing legislation but also allows the FAES to carry on its current activities under the authority of the Foundation.

18. Fair Value of Financial Instruments

Accounting Standards Codification (ASC) Topic 820 provides a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 Inputs to the valuation methodology are unadjusted quoted market prices for identical assets or liabilities in active markets that the Foundation has the ability to access.

Level 2 Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

Following is a description of the valuation methodologies used for assets measured at fair value.

U.S. government bonds; exchange traded funds:

Valued at quoted market price per number of units/shares held at year-end.

Equity mutual funds; bond mutual funds

Valued at net asset value (NAV) of shares held at year-end.

All assets have been valued using a market approach. Fair values for assets in Level 2 are calculated using quoted market prices for similar assets in markets that are not active. There were no changes in the valuation techniques during the current year.

The preceding methods described may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, although the Foundation believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different fair value measurement at the reporting date.

The following sets forth by level, within the fair value hierarchy, the Foundation's assets at fair value as of December 31, 2020 and 2019:

	Assets at Fair Value as of December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. government bonds	**$ 41,959,728**	**$ -**	**$ -**	**$ 41,959,728**
Equity mutual funds	**11,292,036**	**-**	**-**	**11,292,036**
Bond mutual funds	**4,029,251**	**-**	**-**	**4,029,251**
Exchange traded funds	**2,355,265**	**-**	**-**	**2,355,265**
Total investments	**$ 59,636,280**	**$ -**	**$ -**	**$ 59,636,280**

	Assets at Fair Value as of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. government bonds	$ 72,119,707	$ -	$ -	$ 72,119,707
Equity mutual funds	10,890,405	-	-	10,890,405
Bond mutual funds	3,189,744	-	-	3,189,744
Exchange traded funds	1,947,293	-	-	1,947,293
Total investments	$ 88,147,149	$ -	$ -	$ 88,147,149

19. Conditional Grant Awards

The Foundation has authorized conditional scientific grants under the following programs as of December 31:

	2020	2019
Accelerating Medicines Partnership: Type 2 Diabetes	$ **187,500**	$ 1,819,974
Accelerating Medicines Partnership: Parkinson's Disease	**295,444**	333,431
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**3,002,968**	2,082,140
iUFV (Combining Epitope-Based Vaccine Design with Informatic	**383,942**	-
Using Biomarkers to Predict TB Treatment Duration	**973,926**	2,743,406
GeneConvene	**2,327,641**	-
Biomarkers Consortium – Cardiac Troponin Project	**13,454**	43,454
Biomarkers Consortium – Bone Quality Project	**-**	55,000
Biomarkers – Target BMx	**137,618**	355,333
LungMaP (Lung Cancer Master Protocol)	**376,590**	50,000
Osteoarthritis (OA) Biomarkers Qualification (OA BMxQ)	**56,228**	151,329
Accelerating Medicines Partnership: Alzheimer's Disease	**2,681,500**	4,159,250
Efficay of Heterodimeric IL-15 Treatment Regimens	**940,671**	1,741,317
Understanding the Mechanisms of Intravenous BCG-induced Protection against TB in NHP	**2,286,767**	803,722
NIH Travel for Gates (FNIH Travel support for NIH Scientists)	**139,739**	139,739
Comprehensive Cellular Vaccine Immune Monitoring Consortium	**534,936**	2,625,249
CAR-T	**1,313,141**	-
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines	**810,000**	-
	$ 16,462,065	$ 17,103,344

These authorized awards would become a liability to the Foundation in the future, if the grantees meet certain conditions, including the Foundation's satisfaction with and approval of progress reports.

20. Leases

In January 2017, the Foundation entered into a new lease agreement with Hines USVF North Bethesda Place LP for a fifteen-year period which expires October 31, 2032. This lease is effective November 2017 and contains a rent abatement period for the first seven months.

In June 2019, the Foundation entered into a new lease agreement with Hines USVF North Bethesda Place LP for a twelve-year period which expires October 31, 2032. This lease is effective January 2020 and contains multiple rent abatement periods.

In December 2019, Lithium, LLC purchased the properties above from Hines USVF North Bethesda Place LP and became the lessor, no changes were made to the lease agreements.

Rent expense was $749,860 and $564,954, respectively, for 2020 and 2019.

The future minimum lease payments required under the operating leases for the years ending December 31, are as follows:

2021	$ 847,247
2022	722,172
2023	618,939
2024	919,084
2025	944,357
Thereafter	6,699,677
	$ 10,751,476

21. Risks and Uncertainties

The Foundation invests in various investment securities. Investment securities are exposed to various risks, such as interest rate, credit and overall market volatility risks. Due to the level of risk associated with certain securities, it is at least reasonably possible that changes in the values of investment securities will occur in the near term and such changes could materially affect the Foundation's account balances and amounts reported in the statements of financial position.

In March 2020, the World Health Organization declared the outbreak and spread of COVID-19, a novel strain of coronavirus, a pandemic. The coronavirus outbreak has had far reaching and unpredictable impacts on the global economy, supply chains, financial markets, and global business operations of a variety of industries. Governments have taken substantial action to contain the spread of the virus including mandating social distancing, suspension of certain gatherings, and shuttering of certain nonessential businesses. The extent to which it will impact the Foundation going forward will depend on a variety of factors including the duration and continued spread of the outbreak, impact on donors, employees and vendors, as well as governmental, regulatory and private sector responses. Further, the pandemic may have a significant impact on management’s accounting estimates and assumptions. The financial statements do not reflect any adjustment as a result of the increase in economic uncertainty.

Foundation for the National Institutes of Health, Inc.

Compliance Section

Year Ended December 31, 2020

DHG

Independent Auditors' Report on Internal Control Over Financial Reporting and on Compliance and Other Matters Based on an Audit of Financial Statements Performed in Accordance With *Government Auditing Standards*

Board of Directors
Foundation for the National Institutes of Health, Inc.
North Bethesda, MD

We have audited, in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of Foundation for the National Institutes of Health, Inc. (a nonprofit organization), which comprise the statement of financial position as of December 31, 2020, and the related statements of activities, functional expenses and cash flows for the year then ended, and the related notes to the financial statements, and have issued our report thereon dated May 20, 2021.

Internal Control over Financial Reporting
In planning and performing our audit of the financial statements, we considered Foundation for the National Institutes of Health, Inc.'s internal control over financial reporting (internal control) as a basis for designing the audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of Foundation for the National Institutes of Health, Inc.'s internal control. Accordingly, we do not express an opinion on the effectiveness of Foundation for the National Institutes of Health, Inc.'s internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

Compliance and Other Matters

As part of obtaining reasonable assurance about whether Foundation for the National Institutes of Health, Inc.'s financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the financial statements. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the organization's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the organization's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Dixon Hughes Goodman LLP

Richmond, VA
May 20, 2021

DHG

Independent Auditors' Report on Compliance for the Major Program and on Internal Control Over Compliance Required by the Uniform Guidance

Board of Directors
Foundation for the National Institutes of Health, Inc.
North Bethesda, MD

Report on Compliance for the Major Federal Program
We have audited Foundation for the National Institutes of Health, Inc.'s compliance with the types of compliance requirements described in the *OMB Compliance Supplement* that could have a direct and material effect on Foundation for the National Institutes of Health, Inc.'s major federal program for the year ended December 31, 2020. Foundation for the National Institutes of Health, Inc.'s major federal program is identified in the summary of the auditors' results section of the accompanying schedule of findings and questioned costs.

Management's Responsibility
Management is responsible for compliance with the requirements of laws, regulations, contracts, and grants applicable to its federal programs.

Auditors' Responsibility
Our responsibility is to express an opinion on compliance for Foundation for the National Institutes of Health, Inc.'s major federal program based on our audit of the types of compliance requirements referred to above. We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and the audit requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Those standards and the Uniform Guidance require that we plan and perform the audit to obtain reasonable assurance about whether noncompliance with the types of compliance requirements referred to above that could have a direct and material effect on a major federal program occurred. An audit includes examining, on a test basis, evidence about Foundation for the National Institutes of Health, Inc.'s compliance with those requirements and performing such other procedures as we considered necessary in the circumstances.

We believe that our audit provides a reasonable basis for our opinion on compliance for the major federal program. However, our audit does not provide a legal determination of Foundation for the National Institutes of Health, Inc.'s compliance.

Opinion on the Major Federal Program
In our opinion, Foundation for the National Institutes of Health, Inc. complied, in all material respects, with the types of compliance requirements referred to above that could have a direct and material effect on its major federal program for the year ended December 31, 2020.

DHG

Report on Internal Control over Compliance

Management of Foundation for the National Institutes of Health, Inc. is responsible for establishing and maintaining effective internal control over compliance with the types of compliance requirements referred to above. In planning and performing our audit of compliance, we considered Foundation for the National Institutes of Health, Inc.'s internal control over compliance with the types of requirements that could have a direct and material effect on each major federal program to determine the auditing procedures that are appropriate in the circumstances for the purpose of expressing an opinion on compliance for each major federal program and to test and report on internal control over compliance in accordance with the Uniform Guidance, but not for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, we do not express an opinion on the effectiveness of Foundation for the National Institutes of Health, Inc.'s internal control over compliance.

A *deficiency in internal control over compliance* exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. A *material weakness in internal control over compliance* is a deficiency, or combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of the internal control over compliance was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies. We did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of the Uniform Guidance. Accordingly, this report is not suitable for any other purpose.

Dixon Hughes Goodman LLP

Richmond, VA
May 20, 2021

Foundation for the National Institutes of Health, Inc
Schedule of Expenditures of Federal Awards
For the Year Ended December 31, 2020

Federal Grantor/Pass-through Grantor/Program or Cluster Title	CFDA Number	Grant Number	Pass-through Entity ID Number	Expenditures	Subrecipient Awards
Research and Development - cluster					
Office of Strategic Coordination - National Institutes of Health					
Direct Program:					
COVID-19 - Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)	N/A	OT2 OD030195	N/A	$ 3,614,477.00	$ -
Total Expenditures of Federal Awards				$ 3,614,477.00	$ -

See independent auditors' report.

Notes to Schedule of Expenditures of Federal Awards

1. Basis of Presentation

The accompanying Schedule of Expenditures of Federal Awards (Schedule) includes the federal grant activity of Foundation for the National Institutes of Health, Inc. (Foundation) under programs of the federal government for the year ended December 31, 2020. The information in this schedule is presented in accordance with the requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Therefore, some amounts presented in this schedule may differ from amounts presented or used in the preparation of the basic financial statements. Because the schedule presents only a selected portion of the operations of the Foundation, it is not intended to and does not present the financial position, changes in net assets, or cash flows of the Foundation.

2. Summary of Significant Accounting Policies

The accompanying schedule of expenditures of federal awards is presented using the accrual method of accounting. Such expenditures are recognized following the cost principles contained in the Uniform Guidance, wherein certain types of expenditures are not allowable or are limited as to reimbursement. The Foundation has elected to not use the 10-percent de minimus indirect cost rate as allowed under the Uniform Guidance.

3. Contingency

The grant revenue amounts received and expensed are subject to audit and adjustment. If any expenditures are disallowed by the grantor as a result of such an audit, any claim for reimbursement to the grantor would become a liability of the Foundation. In the opinion of management, all grant expenditures are in compliance with the terms of the grant agreements and applicable federal and state laws and regulations.

Schedule of Findings and Questioned Costs

1. Summary of Auditors' Results

a. An unmodified opinion was issued on the financial statements.

b. There were no significant deficiencies or material weaknesses in internal control disclosed by the audit over financial reporting.

c. The audit did not disclose any noncompliance that would be material to the financial statements.

d. There were no significant deficiencies or material weaknesses in internal control over the major program to disclose.

e. An unmodified opinion was issued on compliance for the major program.

f. The audit did not disclose any audit findings required to be reported in accordance with Uniform Guidance.

g. The major program is:

COVID-19 - Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

h. The dollar threshold used to distinguish between Type A and Type B programs was $750,000.

i. The auditee did not qualify as a low-risk auditee under Section 200.516 of OMB2CFR Part 200.

2. Findings Relating to the Financial Statements which are Required to be Reported in Accordance with Governmental Auditing Standards

None

3. Findings and Questioned Costs for Federal Awards

None

4. Status of Prior Year Findings

The Foundation did not have a Single Audit in 2019.

Annual Report

Access at
fnih.org/2020annualreport

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