2021 Statutory Report

FNIH

Foundation for the
National Institutes of Health

Contents

Tab One
FNIH Overview

FNIH
Foundation for the
National Institutes of Health

The Foundation for the National Institutes of Health 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 Foundation, also known as the FNIH, attracts and shares resources, organizes and administers research programs and consortia, enables insight and innovation, supports training and education, distributes expertise, and disseminates knowledge supporting a wide range of health challenges.

In the past 26 years, the Foundation has raised over $1.4 billion from the private sector to support the NIH and advance NIH-related research initiatives. The FNIH continues to earn the top designation of four-star honors from the Nation's largest independent charity evaluator, Charity Navigator, a clear indicator that the FNIH carries out its mission in a way that is financially efficient, uses sector best practices, and "exceeds industry standards."

As the COVID-19 pandemic continued into 2021, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership forged ahead. In June 2021, ACTIV-6, a new master clinical trial protocol, launched to help researchers understand how existing medications can improve symptoms and limit hospitalizations for people with mild-to-moderate COVID-19. In addition, NIH ACTIV trial sponsors, ACTIV working group leaders, and ACTIV trial representatives began to develop new strategies for future ACTIV trials in outpatient and inpatient settings and to address Long COVID. House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) stated that FNIH's work to "coordinate the ACTIV program that is strategizing our research and prioritizing and speeding development of the most promising COVID-19 vaccines and treatment" had "played [an] important role in our Nation's fight against COVID-19." Representative Richard Hudson (R-NC) stated that the FNIH was critical in "forging partnerships between the Federal Government and private industry experts" and that "due to partnerships such as these, we have already seen the success of the ACTIV program in speeding developments of COVID-19 vaccines and treatments."[1]

In addition, two new programs under the Accelerating Medicines Partnership (AMP®) launched in 2021. The Bespoke Gene Therapy Consortium (BGTC), seeks to accelerate the delivery of promising new gene therapies to patients with rare diseases that currently lack effective treatments. It is a collaboration of the NIH, the Food and Drug Administration (FDA), the pharmaceutical industry, and patient organizations. In addition, the Accelerating Medicines Partnership Autoimmune and Immune-Mediated Diseases (AMP® AIM) program will advance our understanding of key disease pathways using new tools to map in three-dimensions how cell types, cell states, and cell-to-cell interactions network to cause inflammation, abnormal function, and tissue injury.

The FNIH celebrated the achievements of many clinicians, scientists, and partners in our research activities, including Dr. Xiaowei Zhuang, winner of the Lurie Prize in Biomedical Sciences, and Dr. Piro Lito, recipient of the Trailblazer Prize for Clinician Scientists. The FNIH also honored Janssen Research & Development, LLC, and the eight ACTIV Working Group Co-Chairs by naming them recipients of the Charles A. Sanders, M.D., Partnership Award.

The FNIH also celebrated the leadership and contributions of Dr. Maria C. Freire, who stepped down as President and Executive Director in September 2021 after nine remarkable years. Said Dr. Steven M. Paul, FNIH Chairman, "Maria leaves the Foundation in a very strong position, having established it as a leader in advancing biomedical research worldwide. She has created a legacy of making a difference in people's lives and leaves the Board and the FNIH staff an inspired roadmap for the future."

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[1] 167 CONG. REC. H6694-6695 (Nov. 30, 2021), *available at* https://www.congress.gov/congressional-record/2021/11/30/house-section/article/H6694-1.

Tab Two
Board of Directors

FNIH
Foundation for the
National Institutes of Health

FNIH
Foundation for the
National Institutes of Health

Board of Directors

as of December 31, 2021

Steven M. Paul, M.D. (Chairman)
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David Wholley, M.Phil.
Interim President and Executive Director, Foundation for the National Institutes of Health

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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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Director Emeritus, Albert & Mary Lasker Foundation

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Chief Executive Officer, Ruder Finn Inc.

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Director Emeritus, Sasha Bruce Youthwork, Inc.

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

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Executive Director, Center for Audit Quality

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

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Harold T. Shapiro Distinguished University Professor, University of Michigan

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

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Chairwoman, Edmond J. Safra Philanthropic Foundation

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Retired Chairman and Chief Executive Officer, Glaxo Inc.

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President and Chief Operating Officer, Beacon Capital Partners

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Chairperson, Friends of Cancer Research

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

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Retired Executive Vice President and Chief Scientific Officer, Johnson & Johnson

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

EX OFFICIO NON-VOTING DIRECTORS

Lawrence A. Tabak, D.D.S., Ph.D.
Acting Director, National Institutes of Health

Janet Woodcock, M.D.
Interim Commissioner, Food and Drug Administration

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Cahill Professor in Biochemistry (Emeritus), Stanford University School of Medicine

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Founder and Chief Executive Officer, The Sherry Lansing Foundation

Paul M. Montrone, Ph.D.
Chairman, Perspecta Trust

The Honorable John Edward Porter
Partner, Hogan Lovells US, LLP

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

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Member of the Center for Assessment Technology and Continuous Health, Massachusetts General Hospital

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
Foundation for the National Institutes of Health

NIH-FNIH Steering Committee 2021 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 are vetted by the Agency before transmittal to the Foundation. The final step in its 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 2021. 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.

All of Us **Research Program** (RFC[1] received on August 11, 2021, from the Office of the Director (OD)): This project endeavors to promote diversity in the biomedical research workforce through training opportunities using the *All of Us* Research Program dataset. It aims to equip students and researchers at Minority Serving Institutions (MSIs) with the tools, skills, and knowledge to navigate and utilize one of the largest and most diverse biomedical databases in the world and is focused on helping to position these researchers to contribute broadly to the biomedical research ecosystem and enable future medical discoveries. As part of its due diligence, the FNIH spoke with relevant private and philanthropic organizations to elicit feedback and evaluate the potential for funding. Eager to see NIH play a bigger role in diversifying the biomedical research workforce, the organizations indicated generally good alignment with their priorities. On February 22, 2022, this project was conditionally approved by the FNIH to go forward in a pre-planning phase to include MSIs and other key stakeholders, with a 12-month commitment to fundraising and project development subsequent to completion of planning, which may be extended by mutual agreement.

Medical Student Research Fellowship Program (MSRFP) (RFC[1] received on August 18, 2021 from the Office of the Director (OD)): Conceived by the Physician Scientist Support Foundation (PSSF) as an extramural counterpart to the NIH's own Medical Research Scholars Program, the MSRFP aims to increase the number of talented physician-scientists and enhance diversity among this workforce. Because the PSSF is a very young non-profit without full-time staff, PSSF and NIH asked the FNIH to provide project management services to the program during an initial two-year period, during which PSSF would establish its infrastructure and prepare to take over full control of the MSRFP. In April 2022, after successfully securing funding on its own and upon further consideration, PSSF elected to launch and manage the MSRFP immediately, without reliance on the FNIH.

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

Tab Four
Project Summaries as of December 31, 2021

FNIH
Foundation for the National Institutes of Health

FNIH PROJECT SUMMARIES

TABLE OF CONTENTS

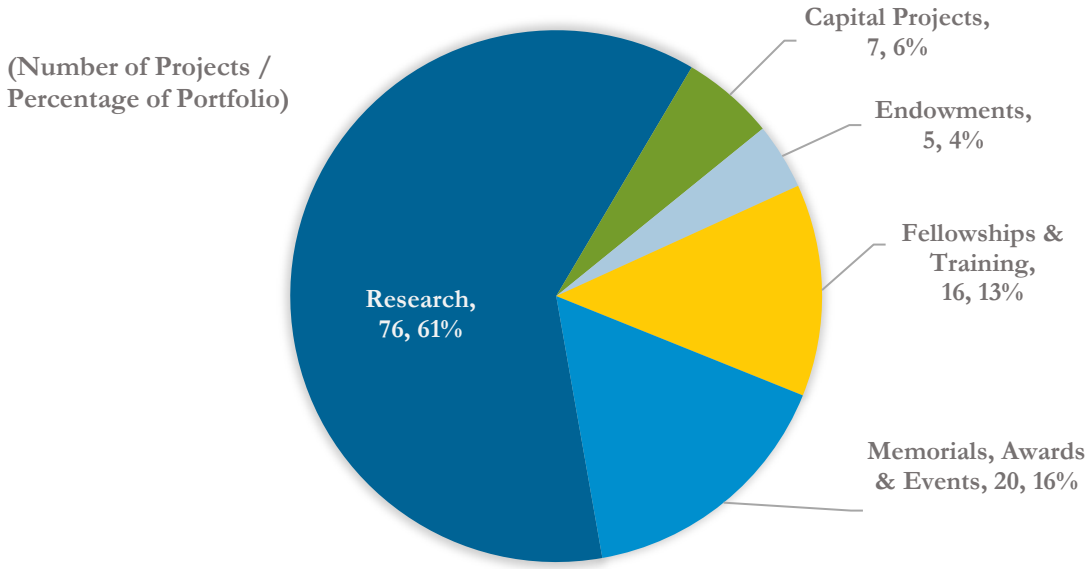
FNIH
Foundation for the National Institutes of Health

Project Summaries

as of December 31, 2021

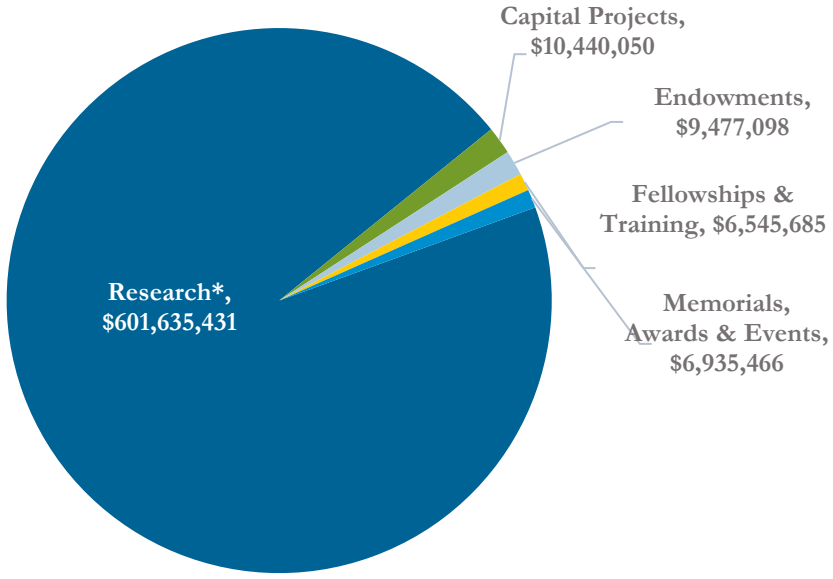
Number of Current Projects by Activity Type

124 Projects



Current Project Funding by Activity Type

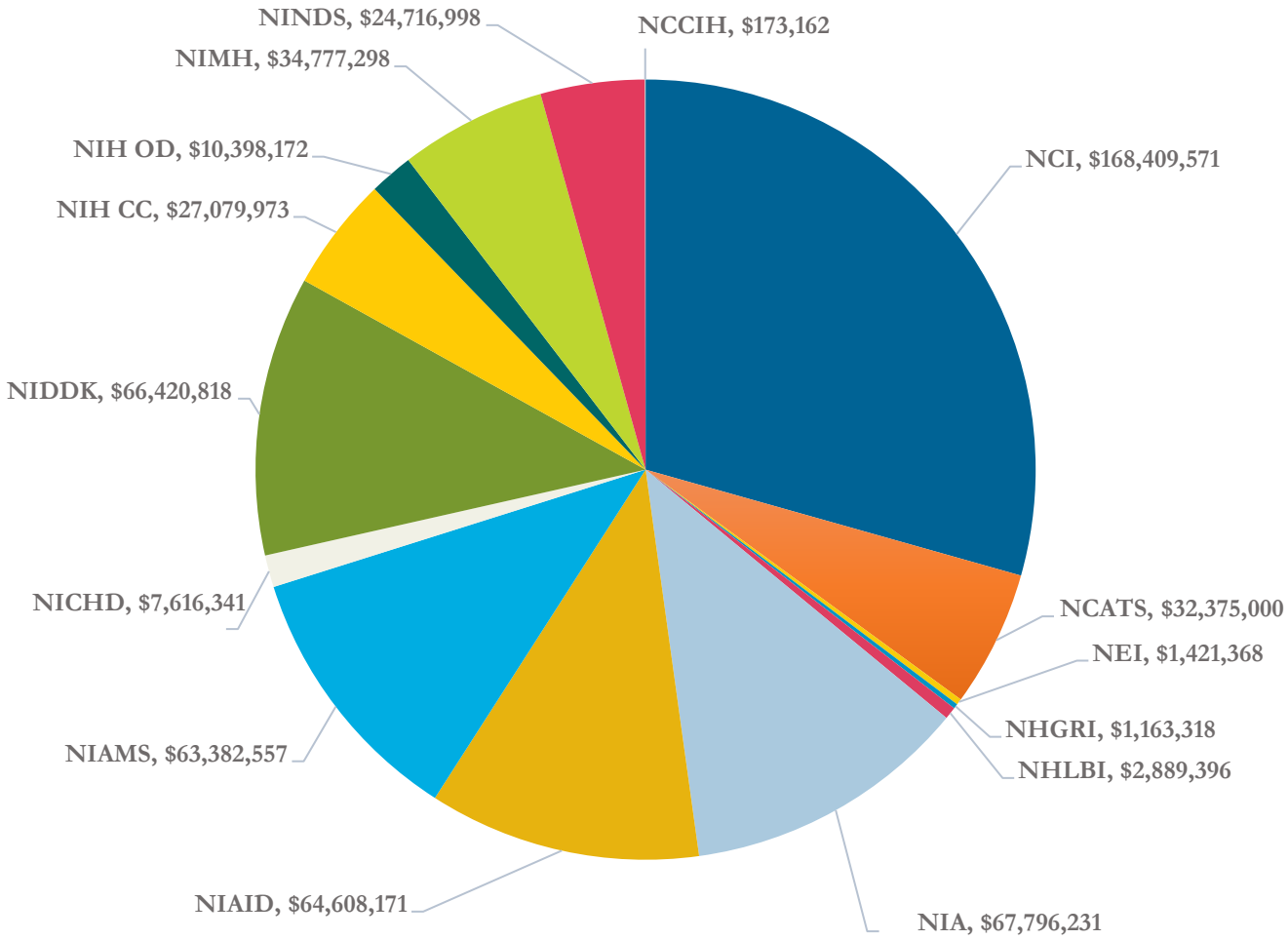
Since project inception ~$635 million



*Includes ~$8.09 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 ~$573.2 million §



§ The remaining ~$61.8 million is not specifically associated with an Institute or Center. See "Other" section.

OFFICE OF THE DIRECTOR

Office of the Director

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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. Multiple ACTIV master protocols for COVID-19 treatments are underway.	ACTIV continues to focus on two main areas of investigation: Therapeutic clinical trials and viral variant tracking. The management of 9 ACTIV clinical trial master protocols for COVID 19 therapeutic interventions has continued. Details of these trials can be found at this website: https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials. A program in tracking viral variant emergence and evolution (TRACE) continues to assess emerging mutations in the viral population and to collect variant effects on therapeutic and vaccine efficacy.	$7,732,600*	Apr-20
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 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.	This project closed at the end of 2021 Q3.	$357,995*	Apr-18
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Oxford Cambridge Scholarship Program	NIH developed a graduate training program in collaboration with the University of Oxford and the University of Cambridge in England. Trainees spend part of their time at NIH and part at Oxford or Cambridge, the degree granting institutions. 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.	No updates in Q4.	$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.	No Q4 2021 activity.	$38,350	Nov-08

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Amgen NIH Scholars Program	Amgen sponsors undergraduate research scholars to participate in NIH's Summer Internship Program. The program began in June 2015. The Program has 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.	Funds for the 2022 program have been sent to the FNIH and transfer will be made to the NIH pending the request from NIH program management. Applications for the 2022 program have closed and scholars will be chosen and notified by March 1, 2022.	$1,578,823	Jun-14
JKTG Foundation - Post-Bacc and Graduate Intramural Research Training Fellows	The Jayne Koskinas Ted Giovanis Foundation for Health Policy (JKTG Foundation) provides scholarship support of two young investigators in the Office of Intramural Training and Education under the mentorship of Dr. Sharon Milgram.	In Q4 2021, the JKTG Foundation delivered a press release to announce its two new intramural fellows. In Q1 2022, FNIH staff will meet with NIH and the JKTG Foundation to discuss the fellowship and engagement opportunities.	$515,835	Jun-15

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

Numbers are unaudited and subject to change.

New Projects
Closed Projects


NATIONAL
CANCER
INSTITUTE

National Cancer Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	The NiP project leads met on November 11, 2021 and confirmed the completion of Aim 1, triggering Payment 2 for all funding members. Data evaluation continues, with an emphasis on the clinical data integral to Aim 2.	$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.	No updates for Q4.	$1,300,000	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.	The project team met on December 10, 2021 and the principal investigator presented a report on the progress towards completion of Aim 1. Following the call, the project team voted that sufficient progress had been made so as to meet the "12-month milestone" and trigger final project payments. The project team plans to meet again in Q1 2022 to align on project completion expectations, update the project publication plan, and discuss the possibility of a Phase II trial. Phase I is expected to complete in early Q2 2022.	$1,957,386	Apr-18

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Biomarkers Consortium - Integrated Radiogenomics for Virtual Biopsy and Treatment Monitoring in Ovarian Cancer	High-grade serous ovarian carcinoma (HGSOC) is a major clinical problem with a mortality rate similar to lung and pancreatic cancer. The lack of robust and biologically validated imaging biomarkers for HGSOC leads to poor assessment of treatment response in routine clinical practice and clinical trials. Currently, RECIST and CA 125 measurements are widely used but RECIST measurements do not distinguish responses between sites of metastasis and CA 125 lacks specificity and overestimates treatment response. The Multi-Omics project will develop and validate predictive and prognostic biomarkers to optimize response assessment for patients with HGSOC by using advanced data analytics and data visualization methods to quantify and integrate radiomics and molecular data. The team will apply novel image-guided tissue sampling methods to defined radiomic areas within the tumor mass to reveal the biological meaning of quantitative imaging features. These cutting-edge imaging tools for tumor sampling will be introduced into clinical trials, which will enable greater understanding of tumor biology during treatment and improve therapy selection and patient outcomes.	The project scan in preparation for EC plan evaluation was not reviewed favorably. The project team revised the plan to remove the phase 3 prospective evaluation and reduce the budget to $4.9 M. In Q4 2021 and Q1 2022 the team is working with companies to explore further cost reductions and industry participation in the project. Another funding scan and EC project plan review is planned for Q2 2022.	Fundraising efforts are underway	TBD
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 outlined five sections of the white paper covering advances in technology and MRD measurement, regulatory considerations as explained by a group from FDA and a response section from industry regulatory expertise, and illuminating clinical case studies. After approval of the outline by the CSC on March 31, 2020 and EC on May 22, 2020, drafting amongst subsections started in Q2 2020. All sections are complete including clinical case studies across 4 patient populations, a technology review and an FDA-provided regulatory perspective. The final draft was reviewed by the entire group and updates were made to an accompanying MM trials roster. Final reviews and COI information was collected and the manuscript was accepted for publication in Clinical Cancer Research in June 2021. The WG met after publication for final close out and discussed additional opportunities. A concept is being drafted to evaluate early and smoldering myeloma using MRD as a tool.	$3,693	TBD

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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 received approval from the CSC on June 26, 2018 and the EC on August 16, 2018. The final budget of $1,238,575 reflects in-kind contributions of $1 million 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 March 20, 2018 and April 16, 2018, and in discussions with the FDA on March 26 and July 5. Funding agreements with 5 companies, 2 RCAs, 1 CRADA with the central lab and 1 MOU were executed and the project officially launched September 24, 2019. Additional discussions with the FDA were held on April 6, August 20 and September 28, 2020 to inform the Phase 2 Functional Characterization study and Phase 3 Clinical pilot design. Additional discussion with FDA partners is planned in Q1 2022. Initial performance evaluation data was reviewed with the manufacturing companies and the full project team, and published in the Journal of Clinical Oncology-Precision Oncology June 2020. Phase 2 CSFC study began Q4 2021 with material dilutions and is in progress through Covid-related supply delays. Contract amendments for reallocated funds to two sites and with two material manufacturers to extend the timeline were executed. 13 donated services agreements were executed with external labs for phase 3 clinical participation, and launch of the final phase is expected in Q1 with publication and project close in Q4 2022.	$1,929,736	Apr-18
Biomarkers Consortium - Minimal Residual Disease in Acute Myeloid Leukemia	AML is a heterogeneous genetic disease, with each case harboring ~3-5 functional mutations. However, ~25 genes cover the vast majority of the mutation spectrum. Thus, the biomarkers of MRD cover a variety of mutations which may occur at different frequencies at diagnosis and during therapy given Darwinian selection and clonal selection. This program will work to pioneer sensitive, reproducible, and robust platforms for the measurement of MRD. The project team will review assays for MRD measurement against standard methods and retrospectively collected data, compile best practice and incorporate prospective studies for regulatory level data collection. Step one will create a library of reagents that can be a continuing source of truth against which new MRD technologies can be tested, step two will compare these new technologies to paired diagnostic/remission samples which already have MRD testing performed by a benchmarked method, and step three will incorporate those technologies into prospective trials for for collection of data that can be used in regulatory decision making.	In addition to four previously executed LOAs, three additional LOAs were executed during Q4 2021, with one more expected for Q1 2022. Eight companies are expected to come in with in-kind support for the project, with two already having executed contracts and two more planning partial funding and partial in-kind support. With these expected 16 partners, the project is now funded beyond the initially planned budget, and the project team is evaluating how to use the additional funds. Project launch is scheduled for January 31, 2022, after which monthly subgroup meetings and readouts to the full project team will begin.	$5,250,000	TBD
Biomarkers Consortium - 2021 Cancer Prevention Workshop	The Biomarkers Consortium 2021 Cancer Prevention Workshop was developed between the FNIH, the National Cancer Institute, and the Division of Cancer Prevention (NCI). Its purpose was to gather to gather information about interest and activity in cancer prevention on behalf of the Division of Cancer Prevention (DCP within NCI).	The workshop took place on November 12, 2021 and attracted over 100 attendees, providing a valuable venure at which to gather and share cancer prevention knowledge, with the ultimate goal of providing this information to the Division of Cancer Prevcention within the NCI.	No funds were raised. Unused funds were transferred from a closed project.	TBD

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	Having accomplished all Aims, the Project Team is in the final stages of closing the project and publishing their results. FNIH produced and published a video highlighting the success of the project in Q2 2021. The Final Report summarizing work in Phase 2 was prepared and circulated in Q4 2021. The team has published five manuscripts including a publication on radiomic modelling in colorectal cancer in Q4 2021. An additional manuscript on radiomic modelling and machine learning to predict overall survival in patients with melanoma was published in Q1 2022. The team is finalizing two additional publications. A concept proposal for a phase 3 project is in progress and is expected to be reviewed by the CSC in Q2 2022.	$3,601,000	Jan-17
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.	In Q4 2021, the FNIH continued stewardship of the Bradley Charity Gift Annuity Fund. In Q1 2022, FNIH will provide an update to the Bradleys.	$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.	In Q4 2021, FNIH staff reached out to Mr. Andrew Steinhaus to introduce him to his new fund manager at FNIH.	$38,813	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.	In Q4 2021, FNIH continued to receive support for this fund. There were no expenditures during Q4 2021.	$2,569,719	Feb-00

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Cancer Steering Committee Annual Scientific Symposium 2021	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. This year's meeting will take place virtually over the course of four days.	The 2021 CSC meeting was held virtually over the course of four days. Topic areas in 2021 included 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. An executive summary of the symposium is publicly available on the FNIH website.	$112,500	Oct-21
Cancer Steering Committee Annual Scientific Symposium 2022	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. This year's meeting will take place virtually over the course of four days.	Planning is underway for a virtual symposium to be held over four days in Fall 2022. Topic areas and speakers will be researched in Q1 2022. A tentative agenda will be set in Q2 2022.	Fundraising efforts are underway	
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-in fected 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 antiretrov iral regimens and/or eliminating the risk of further transmission of the virus.	We have entered the final Award year and anticipate a timely completion. The potential for a No Cost Extension is available, if deemed necessary. A virtual HIV Cure Summit is being hosted by Gilead to determine if additional funding is needed. The Year 5 Interim Reports were submitted last year showing promising scientific progress.	$2,874,832	Dec-16

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	In Q4 2021, FNIH staff reached out to Dr. Louis Staudt and Dr. Wyndham Wilson to learn of research progess in follicular lymphoma to share with Fund donors. FNIH staff to follow up with Drs. Staudt and Wilson in Q1 2022 for their report.	$122,500	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.	In Q4 2021, the FNIH continued stewardship of the Gramlilch Melanoma Research Trust and received confirmation of the forthcoming annual distribution in support of melanoma research.	$425,491	Jun-08
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.	In Q4 2021, FNIH staff met with Mr. Bruce Lee of Driven to Cure (DTC) to get an update on DTC's fundraising activity in support of HLRCC research. In Q1 2022, FNIH staff will meet with Dr. Linehan to discuss fund designation.	$1,002,510	Nov-13
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).	As of February 18, 2022, 2325 patients have been registered /screened under the LUNGMAP screening protocol and 49 patients have registered to the S1900E sub-study with Amgen. Lung-MAP has another active sub-study, S1800D with ImmunityBio, which activated on February 15, 2022. Lung-MAP currently has 2 sub-studies in development. The first, S1900F (redesign of S1900B), is slated for activation in Q2 of 2022 and the second, S1900H, is targeting activation in early 2023. FNIH continues to support meetings for the Policy, Trial Oversight, Accrual Enhancement, and Drug Selection committees. Furthermore, the Lung-MAP team is working on restructuring the project to address the changing landscape Lung-MAP faces, assess the direction of the project, and discuss how best to move forward.	$81,662,845	Jun-14

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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-identification, including data from approximately 34,000 patients. The FNIH transferred $230,000 to NCI in April 2019 to cover de-identification costs for the 23 datasets; de-identification is currently underway and data are being uploaded. Through Q4 2021, 21 of the 23 datasets with data from approximately 33,000 patients are now available to the public and scientific researchers that previously were not. The original total project budget was $683,953, of which $420,000 has been raised to date. An additional 12 datasets have been identified as eligible/needing de-identification. The FNIH is evaluating possibilities for supporting a portion of these datasets, as well as sending updates on the project to the current funding partners.	$420,000	Sep-16
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.	To-date, PACT has assayed 2,175 PACT samples with assay data ingested into the CIDC. In 2021, PACT delivered the first version of a specimen management system and a CIDC data center with NIST Moderate security and nine bioinformatics pipelines. Currently 12 trials representing 826 participants and 4,630 individual samples are represented in the CIDC (https://portal.cimacnetwork.org). This year PACT released 2nd Novel Biomarker RFA, received 8 applications, of which 2 were awarded. The awardees started their projects in October 2021. 4 joint manuscripts on CIMAC-CIDC correlative studies published: 1 CIMAC-CIDC overview and 3 on harmonization projects. Approximately 20 additional projects added data in 2021 and are expected to yield publications. In November 2021, PACT held a public webinar on PACT assay harmonization efforts, which was shared with partners for distribution, as well as on the FNIH website and through social media channels. On November 16-17, PACT also held a very successful Joint PACT-CIMAC -CIDC meeting, with participation from all academic, public and private partners.	$60,367,865	Feb-18
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.	The fund continued receiving support through Q4 2021.	$807,343	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.	No Q4 2021 activity.	$22,500	May-15

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	A No Cost Extension is being considered to aid in continued research. Any extension is pending a potential end date. A virtual HIV Cure Summit hosted by Gilead will determine if additional funding is needed. The update in January 2022 demonstrated effective ART treatment in infected subjects and will require repeating to confirm success. Next Quarterly update April 21, 2022.	$1,979,348	Jan-18
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, Dr. Stuart Yuspa informed FNIH staff that the Australian Academy of Science will seek applicants in 2022 and that he will continue organizing the award after he retires at the end of 2021.	$28,747	Jan-03
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.	In Q4 2021, FNIH staff informed Dr. Bob Roberts that the 2021 Anita Roberts Lecture will take place on Monday, November 1, 2021, from 1:00 – 2:30 pm. The speaker will be Dr. Michele K. Evans, Chief of the Health Disparities Research Section, Laboratory of Epidemiology and Population Science, NIA.	$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.	No Q4 2021 activity.	$3,980	Sep-06

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	In Q4 2021, FNIH staff sent a progress report on the 2020 awardees' research to the donor. FNIH staff met with Center for Cancer Research staff to strategize a plan for 2022 donor cultivation.	$500,000	Jan-18
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	No Q4 2021 activity. In Q1 2022, FNIH staff will inquire of the Fund and its support of the next Schatzkin Lecture.	$30,056	Mar-11
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Sallie Rosen Kaplan Memorial Endowment	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.	In Q4 2021, FNIH staff met with Erika Ginsburg at the Office of Training and Education Center for Cancer Training to learn more about the activities of the Sallie Rose Kaplan fund. The FNIH also provided Dr. Jeffrey Rosen, the executor of the Sallie Rose Kaplan estate, a financial and programmatic update on the Kaplan Fund.	$788,080	Jan-99

New Projects
Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(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.	In Q4 2021, Professor Rhonda Magee was the speaker for the annual Stephen E. Straus Award. In partnership with Dr. Mary Bitterman of the Osher Foundation, the FNIH publicized the lecture among the Osher Integrative Medicine Consortium.	$173,162	Jan-07

New Projects
Closed Projects

Numbers are unaudited and subject to change.

NATIONAL
EYE
INSTITUTE

National Eye Institute

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, planning for the 2022 Sayer Vision Research Lecture and Award was initiated with the National Eye Institute (NEI). The FNIH will follow-up with NEI in Q1 2022 to continue planning for the lecture and award.	$421,368	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.	In Q4 2021, Dr. Piatigorsky and the Selection Committee unanimously selected Dr. Dan-Erik Nilsson of Sweden as the inaugural award recipient. FNIH staff began coordinating the logistics for the inaugural lecture and award, which shall take place at NIH's Lipsett Amphitheatre on October 27, 2022.	$1,000,000	Sep-20

New Projects
Closed Projects

Numbers are unaudited and subject to change.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

National Human Genome Research Institute

Research

Project Name	Description	Latest News	Money Raised as of Dec 31, 2021	(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, 2021	(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.	No Q4 2021 activity.	$1,155,000	Oct-11

Fellowships and Training

Project Name	Description	Latest News	Money Raised as of Dec 31, 2021	(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.	No Q4 2021 activity.	$5,583	Sep-11

New Projects
Closed Projects

Numbers are unaudited and subject to change.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

National Heart, Lung, and Blood Institute

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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 is actively working on raising private sector funds to enable a Q1/Q2 2022 launch. Discussions are on going with several pharmaceutical and non-profit partners. The NHLBI portion of this program (HeartShare) is now active with a data translation center at Northwestern University and six clinical sites to enable recruitment. Study protocol is in development.	$220,000	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-sect ional associations of these novel BMs with other novel diabetes, kidney disease and cardiovasc ular 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 recommenda tions 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 July 2022.	With the release of Phase 1 data on glycated albumin last year, the team now has four publications on this biomarker for use in different population groups. Indeed, glycated albumin shows strong potential for use in diagnosing diabetes and could be an excellent measure of glycemic control in people with diabetes. The team also received a journal review showing the importance of this biomarker. The PI is currently working on further manuscripts for the project.	$1,325,000	May-13
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021 FNIH staff scheduled a meeting in Q1 2022 with Mr. Brian O'Neill to discuss the 2022 Boo!Run for Life race event.	$687,921	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.	In Q4 2021, FNIH staff scheduled to meet with Dr. Richard Childs and Dr. Robert Reger in Q1 2022 regarding the use of remaining funds in the Dr. Edward T. Rancic Memorial Fund.	$156,475	Jul-04

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Michael T. Davis Fund	Restricted funds to be received from the estate of Michael T. Davis.	In Q4 2021, the FNIH continued stewardship of the Michael T. Davis estate. FNIH to follow-up with the estate in Q1 2022 regarding a distribution anticipated for Q1 2022.	$500,000	TBD

New Projects
Closed Projects

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NATIONAL INSTITUTE ON AGING

National Institute on Aging

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	AMP® AD 1.0, which launched in February 2014, focused on discovering new therapeutic targets and evaluating the usefulness of tau imaging as a biomarker for disease progression and treatment response. We implemented this AMP AD through two projects: (A) the Biomarkers in Clinical Trials Project and (B) the Target Discovery and Preclinical Validation Project. For Project A, Anti-Amyloid Treatment in Asymptomatic Alzheimer's Disease Trial (A4 Trial) an open-Label Extension Study enrollment continues to collect valuable longitudinal data until the primary efficacy analyses are complete in early 2023, with 48 Tau-Pet scans undergoing quality control in Q4 of 2021. Tau-PET Scan collection is ongoing, and this activity is estimated to conclude by end of 2022.	$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	AMP® AD 2.0, which launched on February 1, 2021, is a partnership that aims to facilitate a true precision medicine approach to target and biomarker discovery. In Q4 2021, AMP AD 2.0 convened three working groups (Experimental Validation Working Group, Single Cell RNAseq Working Group, and Multi-Scale Analyses Framework Working Group) monthly to progress discussion on data analyses and science. The NIA hosted monthly AMP AD 2.0 progress report webinars. The Steering Committee also reviewed the Proteomic Biomarker Development Project presented by Dr. Allan Levey, Emory University. All AMP AD 2.0 project contracts are fully executed. In Q1 2022, FNIH and NIH will coordinate private partners visits with the academic teams.	$13,453,450	Feb-21
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.	ADNI3 amyloid PET add-on study, which launched in July 2019, obtains PET measures that reflect cerebral blood flow in ADNI participants. The goal of this project is to examine the longitudinal change in R1 as a measure of neurodegeneration and also to use early frame data to generate distribution volume ratios (DVRs) for FBB and FBP uptake. Thus, R1 values will be compared to longitudinal change in MRI volumes/cortical thickness and arterial spin labeling as measures of neurodegeneration, and DVRs will be compared to SUVRs to examine longitudinal variability and noise with the expectation that DVRs are superior to SUVRs for longitudinal measures. As of December ADNI3, 100 participants were enrolled in a longitudinal study to examine whether acquisition of FBP and FBB PET data for 20 min immediately following tracer injection could be used to improve longitudinal PET data analysis by modeling perfusion. ADNI will continue follow-up (2 years post baseline) on those who have not completed the study. This approach can be used to estimate regional perfusion, measured as the parameter R1 in simplified reference tissue models.	$825,000	Jan-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	ADNI3 PPSB, which launched in September 2016, builds on the success of previous phases by pursuing new activities that look to identify the earliest changes in brain structure and function that signal its onset and progression of AD. ADNI 3 continues to focus on patient recruitment – particularly for MCI, AD, and minority enrollment. The PPSB Diversity, Equity, and Inclusion Work Group has begun holding monthly meetings. The work group gathers industry DEI experts to help improve enrollment of under represented populations (URPs). The Diversity Task Force (DVTF) has increased enrollment of individuals from URPs. ADNI3 increased from 1.1 to 4 URP enrollments per month, with a goal of 5 URP enrollments per month. Prior to the DVTF, URPs accounted for 12% of ADNI samples, but now they account for 19% of all ADNI3 enrollment. DVTF study sites will continue to enroll URPs for ADNI3 through 2022, but COVID-19 has slowed enrollment. There are 34 sites open (up 3) and able to conduct ADNI3 visits at total capacity. PPSB activities for ADNI 3 have continued. In Q1 2022, the PPSB is planning for the bi-annual ADNI3 PPSB Spring event and Summer meeting.	$15,070,527	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 has received initial data on a subset of samples and expects additional data in Q4 2021. Same issues with the manufacturing of custom kits have delayed the project at least 6 months, but the CRO has been working to find a solution to this supply chain issue. All Aim 1 negotiations and agreements are in place. Planning continues for Aim 2 testing. The project has applied and received approval to analyze matched AD and control participant samples from the well-characterized cohort at Washington University at St. Louis. Contract negotiations are ongoing with a UK CRO are and other sample-contributing research centers.	$1,657,205	Dec-16
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.	The Project Team continued planning the second study, finalizing the sample selection criteria. In Study 2, longitudinal samples from the Alzheimer's Disease Neuroimaging Initiative (ADNI) cohort with at least three blood draws and associated amyloid PET scans will be analyzed to understand how plasma Aβ assays can predict disease progression. The FNIH initiated negotiations with the three vendors whose plasma Aβ assays were prioritized after performing well in Study 1. For the phospho-Tau (pTau) feasibility addendum study, which will assess the performance of a composite biomarker of plasma phospho-Tau and the Aβ peptide measures, the Project Team conducted a due diligence of pTau assay analytical parameters and selected four platforms for inclusion in the project. Additional pTau assays may be considered as they become available for use. The Writing Subgroup submitted a research article on the Study 1 results to the Alzheimer's and Dementia journal. The manuscript concludes that three plasma Aβ assays showed a significant improvement in predicting amyloid positivity over a reference model of known general drivers of amyloid burden alone (Age and ApoE) and furthermore that correlations among assay values for Aβ analytes were moderate to high.	$2,403,433	Apr-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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 Project Team is currently preparing for launch and reviewing opportunities to include new proteomic methods in the biochemical characterization of tissue within the project. The final funding Project Team includes the addition of Biogen and Sanofi who have joined as the final funding members of this project (other organizations include Sage Therapeutics, Alzheimer's Drug Discovery Foundation, Alkermes, Genentech, Takeda, Janssen, AbbVie, and BrightFocus Foundation). With 10 partners the $5.2 million three-year project is fully funded. The FNIH continues to negotiate project service and collaboration agreements in preparation for the project launch. A statistical analysis team has been established and is advancing a detailed statistical analysis plan.	$5,061,766	TBD
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.	Through this longstanding partnership, the NIA and McKnight Brain Research Foundation now jointly support two grants, made by the NIA in September 2021. The awardees are 1) Resilience /Resistance to Alzheimer's Disease in Centenarians and Offspring (RADCO), with PIs Thomas Perls (BU), Stacy Anderson (BU), and Susan Bookheimer (UCLA); and 2) Study to Uncover Pathways to Exceptional Cognitive Resilience in Aging (SUPERAging), with PIs Emily Rogalski (Northwestern), Ghangiz Geula (Northwestern) and Marek-Marsel Mesulam (Northwestern). The grants arose from the NIA's RFA "Network for Identification, Evaluation, and Tracking of Older Persons with Superior Cognitive Performance for Their Chronological Age". Research is now underway.	$5,000,000	Nov-20
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	Development of the NIH Toolkit continues.	$61,850	TBD

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(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.	The FNIH is in the final stages of the project close out process to officially close this project. Contract closing and related partner notifications have been drafted and the appropriate contacts have been identified from the original funding partners. This will allow the process to proceed and be closed by the end of Q1 2022.	$820,000	Jan-11
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 research plan continues as proposed. The VRC will report on neutralization data received in January. The Q1 update was postponed until March awaiting the data and we look forward to positive results during the VRC update.	$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 has a No Cost Extension in place through June 2023 to finish ongoing research at the VRC. The other subawards, Duke and FHCRC, have wrapped up their original No Cost Extension through December 31, 2021. The final reports and financials for closing agreements will be submitted March 2022.	$17,444,918	Jul-16

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Comprehensive Cellular Vaccine Immune Monitoring Consortium (CCVIMC.2.0)	The CCVIMC (Comprehen sive Cellular Immune Monitoring Consortium) was initiated by the FNIH at the NIH Vaccine Research Center (VRC) in 2005 as Central Service Facility (CSF) with the goal of facilitating the translation of vaccine and biologic approaches to HIV prevention emanating from the CAVD through the provision of cutting edge cellular immunologic expertise and assay support. The proposed focus of and support provided by the next iteration of the CCVIMC will address anticipated priorities and needs of the CAVD over the next 5 year that should include the following: 1) Assessment of the T cell immune response generated to a HuCMV vectored HIV vaccine produced by Vir Biotechnol ogies in a Phase 1 clinical trial 2) Expansion of efforts to assess the generation and polishing of VRC01-class antibodies in response to a series of novel immunogens 3) Assessment of novel antigens to stimulate antibody/B cell responses in addition to T cell responses in NHP protocols 4) Continued efforts to develop and understand the protective mechanisms of combination passive antibody prophylaxis	This new iteration of the CCVIMC will run through June 30, 2026. The subaward agreements (with NIAID, Duke and FHCRC) are now in place, although the Research Consortium Agreement still requires signatures from all parties. The next Annual SAB Meeting will take place on May 23-24, 2022 and will be conducted in a hybrid format with approximately 40 in-person attendees.	$14,746,793	TBD
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.	Close-outs for sub-awards are being finalized.	$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

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	A supplemental request is being submitted for NIAID and CHUM to see the trial through the end. The service contract with Bioqual also requires a supplement pending Gates Foundation approval. Another subaward, with FHCRC, will be added to help with the proposed project plan. In January the potential logistics and administrative hurdles were discussed to include FHCRC. The next update is March 9.	$1,460,000	Nov-20
Structure-based Vaccine Design Against HIV-1	This project evaluates structure characteri stics of the trimeric envelope proteins from newly transmitted HIV-1 (transmitt ed-founder [T/F] HIV-1) that are susceptible to broadly neutralizing antibodies (bNAb) and bind to the B cell receptor of corresponding germline ancestor cells. Using this information, proteins will be engineered and evaluated for immunogeni city. Promising candidates will be engineered into a vector-based delivery system and evaluated in small animal and non-human primate models. The project takes advantage of a longitudinal study that has been monitoring a high-risk population in China and aims to develop candidate vaccine immunogens that will elicit bNAbs to the locally circulating HIV strains.	This award ended last year. Final reports were submitted and awaiting approval to move forward with Award close out. There may be an opportunity to work with the same Principal Investigator and the Gates Foundation in the future upon follow-up discussions with the Foundation's Program Officer.	$602,859	Mar-17

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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 NIAID and University of Pittsburgh research teams are dissecting the immune response after IV delivery of bacille Calmette-Guerin (BCG) vaccine and Mtb challenge using a non-human primate model (rhesus macaque). Early results indicated that IV delivery of the BCG vaccine confered a high level of protection when animals were challenged with Mtb. The location and mechanism of immune protection, specifically the T cell response, is under evaluation.	$6,313,721	Jul-18
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.	Project was extended to Oct 2022 to allow for full follow-up of final enrollments in the study.	$12,932,525	Nov-16
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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, and with whom we are working on negotiations with for his final funds transfer, 2) Dr. Djalma de Souza Lima Junior, NIAID, 3) Dr. Diego Fernandez, NIMH, who has received an one-year no-cost extension through 2021, and, 4) Dr. Eunice Dominguez Martin, NINDS.	$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.	In Q4 2021, FNIH staff met with Dr. Jeffrey Cohen to discuss funding opportunities in HV research. FNIH staff to follow up with Mr. Richard Roth in Q1 2022.	$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.	Project closed.	$92,500	Oct-06

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, FNIH staff reached out to Ms. Karen Neva Bell to invite her to view the virtual 2021 FNIH Awards Ceremony. In Q1 2022, FNIH staff will schedule a call to discuss plans for the 2022 Neva Lecture.	$51,059	May-12

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: 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.	The AMP Autoimmune and Immune-Mediated Diseases (AIM) program launched on December 9, 2022. The Partnership includes committed support ($26.5M) from three NIH Institutes (NIAMS, NIAID, NIDCR) and the Office of Research on Woman's Health (ORWH), five not-for-profit partners and 8 pharmaceutical companies (total of $32M from the private sector). NIH has awarded nine individual grants to lead investigators in support of each of the 4 AIM primary disease cores, technical and analytics cores, the sample repository and overall program leadership. Budget agreements are being finalized and awardees will be announced on March 1st. The AMP AIM Steering Committee co-chairs include Bob Carter (NIAMS), Rab Prinjha (GSK), and Mary Collins (Lupus Research Alliance). To increase data sharing, planning and the transition from the AMP RA/SLE to AMP AIM, the program has combined the Steering Committee of these programs to aid and augment planning and decisional input from partners moving forward. The AMP AIM Knowledge and Data Portal is targeted to launch mid-March.	$32,025,000	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/SLE Program remains focused on completing Phase 2 analysis of both the RA and SLE pipeline studies. Grants and contract agreements have been extended through June 2022 to complete efforts on the blood RNA sequencing and multiplex histological analyses (CODEX, Hyperion). Decisions are ongoing regarding migrating or federating data between NIID's ImmPort and the new AMP Autoimmune and Immune-Mediated Diseases program (AMP AIM) portal, which is expected to launch in late March 2022. We have combined the AMP RA/SLE and AMP AIM Steering Committees to maximize data review and strategic decision-making for AIM. The Committee is also planning an early Fall face-to-face meeting as a concluding event to review all data and the program results. Several key publications from the network investigators continue to be published in prolific journals and can be referenced on the FNIH program website.	$27,800,557	Mar-14

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	All MRI and X-ray imaging reads for the project have been completed. In addition, all biochemical marker (serum and urine) analyses of baseline samples (Calcitonin and VIDEO) have been completed. These full datasets are now undergoing analysis by the statistical subteam. Project costs savings have enabled the team to also measure 12-month biochemical samples and assess the change over time (baseline-12 months) in serum and urine proteins as a prognostic marker of OA progression. The project team is currently drafting both biochemical and bone trabecular texture qualification plans for submission to FDA in Q2 2022. A comprehensive project progress update will be presented at a plenary session at the upcoming Osteoarthritis Research Society International (OARSI) in Berlin in early April. The team also expects FDA final review and feedback on the MRI and X-ray qualification plan submitted in late 2020, significantly delayed by the COVID pandemic. Approval of this plan and continued engagement with the FDA will be critical for alignment of the ongoing statistical analysis and final package submission for qualification of the imaging biomarker(s).	$2,282,000	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.	Patient serum samples collected as part of the NIH TARGET Trial have been tested for proteomic biomarkers of RA and cardiovascular disease activity, in-kind, by Crescendo Biosciences (VectraDA) and is ongoing with q2 Solutions/ Rules Based Medicine (Discovery Map) through Q1 2022. Data and results are being returned to lead investigators at the Brigham and Woman's Hospital to be compared and correlated to the NIH TARGET Trial outcomes which are changes in inflammation as measured by vascular FDG PET-CT. Final analysis and data sharing with all project partners is expected in Q2 2022 leading to completion of the project and related manuscripts produced later this year.	$1,275,000	Sep-14

New Projects
Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(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.	All international study sites have ramped up their effort to catch up the enrollment of study participants with the initial weekly enrollment goals after COVID-19 related delays. All institutions submitted their financial and scientific progress reports as requested, evident of the study progressing as planned.	$7,116,341	Oct-19
Biomarkers Consortium: Biomarkers for Early Detection of PreEclampsia	To qualify diagnostic and predictive aangiogenic, imaging and nucleic biomarkers to for early diagnosis and treatment of preeclampsia.	The Preeclampsia project is in active fundraising with 28% funds secured and several positive ongoing conversations. Project launch is planned for Q2 2022.	$500,000	TBD

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(Anticipated) Launch Date**
Biomarkers Consortium: 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 Sjögren's Disease Project research plan development was delayed in late 2021 and early Q1 2022 to seek greater alignment with Sjögren's disease proposed testing in the AMP Autoimmune and Immune-Mediated Diseases (AMP AIM) program. The National Institute of Dental and Craniofacial Research (NIDCR), Oklahoma Medical Research Foundation (OMRF), and industry (Janssen) leaders for the project crossover met with AMP AIM representatives and detailed conversations are ongoing on how best to have this Biomarkers Consortium (BC) project compliment AIM efforts and not duplicate primary objectives focused on spatial transcriptomics using 10X Genomics (Visium) technology or other protein biomarkers. OMRF will also perform the proteomic testing (auto antibodies and serum biomarkers) for the study. It is possible that this project may be incorporated into AMP AIM or samples obtained from AIM could augment this BC study and be done as an ancillary project supported by additional companies. Following final decisions and an agreed upon path forward, the project plan will come forward for Executive Committee review in late Q2 2022.	Fundraising efforts are underway	TBD

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(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.	On November 18, 2021, the FNIH released 4 RFPs seeking genetic, genomic, and other tissues/omics data, and analytic tools for the common metabolic diseases and to make them publicly available in the AMP CMD Knowledge Portal. The FNIH received 25 proposals upon the RFP closing on January 28, 2022. The AMP CMD Steering Committee expects to complete evaluating the proposals by the end of March 2022 and begin the contracting process in Q2 after award recipients are notified. At the end of December 2021 NIDDK made 4 Opportunity Pool awards for a two-year period to investigate genes and functions across cell types. Other: AMP CMD SC and principal investigators of NIDDK-funded Collaborative Awards formed a Partnership Leadership Committee (PLC) in September 2021 and the group meets monthly to discuss science and program gaps and work on ways to address them.	$17,000,000	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.	The AMP T2D Program closed on November 15, 2021. The program accomplished and exceeded its goals and completed under budget. Of the total FNIH budget of $21,775,00 0.00, 81% of it went to investigators' awards, 8% was returned to the 5 industry partners and the rest went to FNIH program management and program related costs. The FNIH had funded 26 projects to investigators in 6 countries. The AMP T2D Steering Committee approved 47 contract amendments to include two scope changes and convened over 200 meetings. It extended the program twice - first in April 2020 to allow the latest round of awards to produce results and then beyond 2020 due to the global pandemic of COVID-19 that had resulted in temporary lockdowns and lab closures. The AMP T2D program has built, within a cloud environment, the AMP T2D Knowledge Portal ("KP"), a powerful open access portal with nexuses at the Diabetes Epigenome Atlas (DGA) and the European Molecular Biology Laboratory, European Bioinformatics Institute (EMBL-EBI) portal, a federated innovation. The three nodes operate seamlessly with each other, allowing query of data across geographical and political boundaries. The KP was publicly available in October 2015, followed by the federated node operational in September 2016 and then DGA in fall 2017. The Program had funded projects that developed methods, advanced analytic tools and visualizations that enable researchers to query traits and genes of interest, prioritize variants and gene populations, gain insights into directional relationships among phenotypic traits, determine causal genes and test hypotheses. FNIH hosted a celebratory meeting with consortium members on December 6, 2021 and featured a commissioned AMP T2D video showcasing its accomplishments.	$21,775,000	Mar-14

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	Lead investigators from Mount Sinai have completed pilot studies for Aim 1 on 22 colectomy samples from 11 patients with pancolitis to determine the degree of variability of inflammation scores, minimum number, and optimal locations of colorectal biopsies needed to achieve accuracy of histologic scores. These results and the statistical modeling supporting the analysis will be presented at Digestive Diseases Week in May and are being drafted into a clinical guidance (white paper) as an initial key deliverable of the project. The FNIH continues negotiations with multiple Pharma companies to provide clinical data and histologic images to validate the findings in Aim 1 and test the ability to resolve ulcerative inflammatory disease and show defined mucosal healing in extant clinical trials. FNIH is aiming to have at least 3 data sharing agreements (DSAs) executed in early Q2 2022. The Project Team has reviewed and selected vendor finalists for the data coordination and machine learning algorithm development in support of Aims 2 and 3 of the project. Multiple manuscripts are now in development including an editorial overview of the program, the modelling paper described above, and a clinical guidance paper focused on a strategy for harmonizing current biopsy protocols across sectors.	$5,381,856	Jun-19
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 Kidney Safety Project Team continues and has finalized the qualification plan for the individual monitoring composite biomarkers of acute kidney injury (AKI) with expected submission to FDA in late Q1 2022. FNIH is contacting the six kidney experts who will review and adjudicate urine biomarker results and data from two prospective trials assessing AKI in patients treated with mesothelioma or aminoglycoside in Q2 2022. FNIH will need to amend outdated contracts and statements of work with each adjudicator and provide a training on the analysis plan. Based on the analysis plan, FNIH is working with the statistical analysis leads to format patient and biomarker results from individual electronic research consent forms and the results database to enable efficient and streamlined adjudication. Results from the adjudication will allow the team to perform the final statistical analysis for the qualification plan. The team is in final review of a manuscript on the initial normal healthy control 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.	$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.	The NIMBLE study met its go/no go criteria based on results from blood-based biomarkers and ultrasound biomarkers. Several abstracts and manuscripts are currently being drafted to share the results widely.	$18,658,184	Jun-19

New Projects
Closed Projects

Numbers are unaudited and subject to change.

NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER

National Institutes of Health Clinical Center

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	The FNIH and NIH are in agreement on the details of a proposed gift from Lilly. Lilly has provided suggested edits which are now under review. It is anticipated that negotiations may be brought to a close within the coming months.	$16,108,629**	Jun-08
Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, FNIH staff spoke with Mr. David Deckers, who said he will be contributing to the Decker Memorial Fund by year end.	$42,910	Jan-03
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, FNIH staff spoke with Dr. Ann Berger regarding the use of funds for the Dr. John L. Barr Fund for Cancer Research. Dr. Berger indicated that the Fund was originally created through a one-time donation to help educate psychology trainees. FNIH staff will contact Mrs. Jill Barr to discuss disbursement in Q1 2022.	$25,384	May-04
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. Scholars arrived on campus in the late summer of 2021. Scholars are working under COVID-19 protocols including social distancing. Research activities are underway. Support for this class of scholars was received from the American Association for Dental, Oral, and Craniofacial Research, Colgate-Palmolive, and the Doris Duke Charitable Foundation.	$463,000	Oct-20

Capital Projects				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, the FNIH met with the Family Lodge staff to discuss needs to be addressed in 2022. FNIH to follow-up with Family Lodge staff in Q1 2022 to discuss current needs.	$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.	No Q4 2021 activity. The FNIH continues to monitor the health of this endowment to determine if any funds are to be utilized to help support programs at the Safra Family Lodge or provide for other needs in 2022.	$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.	No Q4 2021 activity. The FNIH continues to monitor the health of this endowment to determine if any funds are to be utilized to help support programs at the Safra Family Lodge or provide for other needs in 2022.	$750,000	Dec-00
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.	The three Trailblazer Prize finalists were announced in Q4 2021. The winner of the 4th annual Trailblazer Prize for Clinician- Scientists, Piro Lito, M.D., Ph.D., was later announced and honored as part of the virtual 2021 FNIH Awards Ceremony.	$177,047	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.	In Q4 2021, the FNIH met with the Family Lodge staff to discuss needs to be addressed in 2022. In Q1 2022, FNIH will follow-up with the Family Lodge staff to receive an update on current needs.	$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.	The FNIH continues to receive contributions in support of the Safra Family Lodge-All Programs. A fundraising appeal to raise additional funds was active in Q4 2021.	$4,088,318	May-05

Capital Projects				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	In Q4 2021, the FNIH met with the Safra Family Lodge staff to discuss where these funds could be best used. The FNIH and Family Lodge staff will reconvene in 2022 to determine how and when to apply these funds to address a specific need.	$13,982	Jan-04

** This is the value of in-kind goods provided to date.

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

NATIONAL INSTITUTE OF MENTAL HEALTH

National Institute of Mental Health

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	AMP SCZ, which was launched in September 2020, endeavors to provide tools to considerably improve success in developing pharmacologic treatments for patients at clinical high risk for psychosis (abbreviated as CHR). AMP SCZ is the largest effort of its kind and includes 42 recruitment sites across North America, Europe, Asia, and Australia as well as a data processing and analysis center. As of Q4 2021, (1) 24/42 sites received initial IRB approval; (2) Data capture manuals were completed, data workflow tests and training and certifications were underway; (3) Site monitoring plans finalized, and site initiation visits were planned. Site initiation visits include training on (1) protocol, (2) informed consent, (3) required regulatory procedures and review of GCP principles, (4) protocol implementation, and (5) recruitment and retention procedures. In Q1 2022, once site initiation visits are completed, sites will be activated to initiate study enrollment. AMP SCZ will convene the Data Analytic Strategy Working Group with the purpose of bringing together expertise from academic investigators and private partners to finalize the main analytic approaches to successfully fulfill the program primary aims.	$17,000,000	Aug-19

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	Closeout activities at the FNIH continue. A series of video interviews with multiple members of the original ABC-CT 1.0 project team have been recorded. A full video noting the accomplishments of the project and the unique partnership was released in November 2021 and shared widely on social media platforms. All the timepoints were collected for the clinical trial, and the data was cleaned and locked. The primary publications have recently been published in many journals. The N170 and eye-tracking Biomarker Qualification Plan Questions sent to the FDA have received comments and the research teams are reviewing.	$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.	In Q4 2021, FNIH staff provided to Mrs. Deeda Blair financial reports on the Blair Research Initiative and project reports from the award recipients. The FNIH also updated the institutional agreements of award recipient Dr. David Ross of NNCI, in preparation for his transition to a different institution. In Q1 2022, FNIH staff will work with NIMH staff and leadership to determine the awards strategy for 2022.	$15,776,955	Apr-16

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

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, 2021**	**(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.	AMP® PD, which launched on January 30, 2018, encompasses a deep molecular characterization and longitudinal clinical profiling of PD patient data and biosamples to create a resource to identify biomarkers for Parkinson's disease (PD). In Q4 2021, (1) Global Parkinson's Genetics Program provided AMP PD Knowledge Platform users access to federated from their program; (2) AMP PD continued to integrate and quality control untargeted proteomics analyses (3) AMP PD transferred BioFIND cohort cell-free RNA sequencing data. In Q1 2022, AMP PD will (1) will establish a data competition planning committee; (2) coordinate a series of webinars on burgeoning analytical tools; (3) initiate a workshop planning committee; and (4) Regularly convene the Steering Committee, Working Groups, and Subgroups to continue progress on the AMP PD resource development and analyses, including a webinar on sc RNA Brain.	$12,059,453	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 Neurofilament Project is well-positioned to launch in Q1 2022, pending final negotiations of core agreements. The FNIH prepared project launch announcements for release in Rare Disease Month (February). Additionally, the Project Team outlined donor inclusion and exclusion criteria for sample collection and generated a preanalytical sample handling, processing, and storage protocol based on recent publications. The (Letter of Intent) LOI Writing Working Group continued drafting an LOI for submission to the FDA Biomarker Qualification Program. The context of use (COU) was narrowed to focus on neurofilament light and progranulin mutation carriers, characterized to have a sharper increase in neurofilament light before frontotemporal dementia (FTD) disease onset. Hence, the COU was modified to neurofilament light as a Risk/Susceptibility Biomarker to select individuals with progranulin familial FTD mutations at high risk of converting to symptomatic disease for inclusion in a disease-modifying clinical trial.	$1,944,388.00	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.	In Q4 2021, the FNIH and NINDS executed an updated MOU. The remainder of the fund was transferred to NINDS, effectively closing this Fund.	$290,000.00	Nov-13

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
James T. Wendel Fund	Restricted funds to be received from the estate of James T. Wendel.	In Q4 2021, the FNIH continued to facilitate receipt of funds from the James T. Wendel Estate. In Q1 2022, the FNIH staff will formalize a donor agreement and MOU with NINDS and the Wendel Estate regarding the use and distribution of the estate proceeds.	$1,572,600.56	Oct-20
Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	The Congress of Neurological Surgeons Foundation and the FNIH finalized an agreement amendment to continue funding for the K12 NINDS/CNS Getch Scholar through January 2028. Starting in January 2023, there will be an additional scholar funded annually. Dr. Steve Korn of NINDS informed the FNIH that the Getch Scholar awardee for January 2022-December 2023 is Todd Hollon at the University of Michigan.	$400,000.00	TBD
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, FNIH staff arranged a meeting with Ms. Claire Toth to take place in Q1 2022 to discuss development of a new gift agreement and the FNIH Futures Funds.	$7,086,249	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.	No Q4 2021 activity. In Q1 2022, FNIH staff will review the Fund to determine a possible distribution to support multiple sclerosis research.	$60,303	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.	No Q4 2021 activity. In Q1 2022, FNIH staff will meet with NIH and the Newcombs to discuss both the Newcomb lecture and funding for 2022.	$1,304,004	Jan-00

	New Projects
	Closed Projects

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NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

National Center for Advancing Translational Sciences

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership - Bespoke Gene Therapy Consortium (BGTC) (Formerly 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	The BGTC launched on October 27, 2021 with 11 NIH ICs and cross-IC initiatives, 10 companies, and 5 non-profit organizations. Additional for-profit and non-profit organizations have pursued membership since launch. The budget at launch was $76.5M and currently may add up to an additional $8.5M through new partner commitments. The Steering Committee finalized and FNIH published two RFAs for AAV biology research and a submission form for rare genetic diseases that could be included in the BGTC's clinical program on December 2, 2021. All submissions are due February 18, 2022. The SC expects to finalize selection of AAV biology awards in Q2 2022 and 5-6 diseases for clinical trials in Q3 2022.	$32,375,000	TBD

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

	New Projects
	Closed Projects

Numbers are unaudited and subject to change.

FOGARTY INTERNATIONAL CENTER

Fogarty International Center

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
WHO Pandemic Convention Consultations	In May 2021, the World Health Assembly adopted a resolution to hold a special session at the end of November to consider the merits of developing a WHO convention or other agreement on pandemic preparedness. To inform the global community, the FNIH and the O'Neill Institute for National and Global Health Law at Georgetown University is convening high-level technical meetings involving key stakeholders from government, international organizations, academia, civil society, biomedical science, and the private sector focusing on how the current international mechanisms fell short, which legal alternatives (and other collective actions) exist to the current system, and what substantive content a new legal instrument or collective actions could address. The Fogarty International Center expressed interest in providing scientific expertise and perspectives to help inform discussions. The outcomes will include a white paper for circulation to policymakers and introduction at the WHA special session in November along with a set of papers for publication in prominent journals such as The Lancet and JAMA. The consortium will also serve as an expert legal and technical resource for the development of new international tools that can be accessed on an ongoing basis.	The high-level report *Legal Tools for Pandemic Preparedness: WHO Collaborating Center Support for New Coordinating Mechanisms* was published and submitted to the WHO on November 4, 2021. (https://fnih.org/sites/default/files/2021-11/ONL_Pandemic_Prep_D1_P4_0.pdf) Member-states across the globe used the report to review the persistent gaps in surveillance, data, equity, health system resilience, and sustainable financing and to understand the legal possibilities for reform, including the pros and cons of a new pandemic treaty under Article 19 of the WHO Constitution. Thought pieces were published in JAMA (https://jamanetwork.com/journals/jama/fullarticle/2784418), Think Global Health of the Council on Foreign Relations (https://www.thinkglobalhealth.org/article/no-future-shared-future), and Africa Health Journal (https://africa-health.com/wp-content/uploads/2022/02/AH-2022-01-11-global-health.pdf), with additional articles under consideration. Given the World Health Assembly's decision to begin work on a pandemic convention (https://fnih.org/sites/default/files/2021-12/A%20Pandemic%20Treaty%20-%20What%20Comes%20Next%2012.01B.pdf), FNIH, Georgetown University, and WHO have held senior-level discussions on a follow-up project.	Funded from the Pandemic Response Fund	Aug-21

New Projects
Closed Projects

Numbers are unaudited and subject to change.

OTHER

Other

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, FNIH staff contacted Dr. Richard Youle of NINDS to learn of research progress made and to develop a report for the Abrams Charitable Trust in 2022.	$48,953	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 62 contributing members. In Q4 of 2021, all activities were held via teleconference due to COVID-19 including the Executive Committee teleconferences on October 22 and December 10. Steering Committee teleconferences were held by the Cancer Steering Committee (CSC) on October 13 and December 16; the Neuroscience Steering Committee (NSC) on October 14; and the Metabolic Disorders Steering Committee (MDSC) on December 8. There were no meetings of the Inflammation and Immunity Steering Committee (IISC) in Q4 2021. The CSC also held an Annual Symposium that occurred on October 28 and 29 and December 8 and 9.	$28,147,319	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.	In Q4 2021, the winners of the Charles A. Sanders, M.D., Partnership Award (Janssen Research & Development, LLC, and to the eight Co-Chairs of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Working Groups) were recognized at the virtual 2021 FNIH Awards Ceremony.	$3,015,788	May-15
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.	No new updates.	$1,836,845	Jul-16

Research				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
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.	Travel was supported for an NIH investigator in Q4.	$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.	Over the course of 2021 GeneConvene continued its work to support informed decision making about genetic biocontrol approaches for public health by identifying and addressing key questions, providing technical advice, and strengthening capacity and sharing information. This included launching new guidance with WHO, participating in UN meetings on governance of gene drive, co-hosting panel series on social science questions, and sharing information through presentations, webinar series, the Virtual Institute website and newsletter, and social media channels. In the last quarter GeneConvene completed updated guidelines on appropriate containment for research, briefed the Pan American Health Organization on genetic biocontrol approaches, and held the annual meeting of the Gene Drive Research Forum, bringing together experts to discuss stakeholder engagement in risk assessment and regulatory capacity strengthening.	$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.	In Q4 2021, the World Health Assembly (WHA) hosted an historic special session and resolved to negotiate an international agreement on pandemic preparedness and response. To inform and support the WHO in its direction forward, the FNIH and the O'Neill Institute for National and Global Health Law at Georgetown University in September convened over 30 leading experts from across the world for a high-level meeting, supported by the Pandemic Response Fund.	$332,468	Mar-20
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.	The FNIH provides project management and operational support for The Project to Accelerate Novel TB Regimens (PAN-TB) via a grant from the Bill & Melinda Gates Foundation. PAN-TB is a global collaboration of philanthropic, non-profit, and private sector organizations, collaborating on the development of novel TB treatment regimens for all TB patients. 2021 ended with important partner alignment on dosing and the approval of the final protocol for the two regimens currently in the lab phase. In parallel, the collaboration is working on establishing early biomarkers to assess the efficacy of the studied treatments.	$1,270,875	Jun-20

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	This project is now closed.	Support funding received from FNIH internal resources.	Jan-21
Kovler Prize for Excellence in Science Journalism	The Kovler fund explores opportunities for support of journalistic excellence in science, fellowships, forums, and other initiatives which reflect its mission.	In Q4 2021, FNIH staff began developing promotional opportunities for the Quiet Leaders of COVID-19: Shaping the Future of Science forum. FNIH staff also began collaborating with NIMHD staff to coordinate a meeting between the Kovlers, NIMHD leadership and the Kovler's intramural fellow.	$300,000	TBD
Quiet Leaders Forum	During the past year, the public has received ongoing updates on U.S. progress against the COVID-19 virus from leaders and spokespersons from the public and private sectors. While the media has quoted many individuals in the news weekly, sometimes daily, many other remarkable scientists and leaders, with highly respected careers and experience, have been working tirelessly to win the world's epic health battle against SARS-CoV2. Yet their experiences and their stories have not had as much exposure in the national or global press. We want to highlight their valuable, courageous work and their perspectives on the path forward. For this FNIH 25th Anniversary tentpole event, our goal is to offer cross-functional expertise in identifying and focusing on the most critical and high-priority items needed to move beyond this global crisis and achieve preparedness for the future, for all people. The Quiet Leaders of COVID: Shaping the Future of Science, hosted by the FNIH and National Geographic, will stream live as a virtual event on a date in mid-July, based on panelist availability. The event will include two parts—a 60 minute discussion followed by 30 minutes of Q&A. Moderated by Susan Goldberg, Editor-in-Chief of National Geographic, the panel of thought leaders will share their ideas, observations and recommendations based on their personal experiences during the pandemic.	A trailer was created for the Quiet Leaders of COVID forum, which will launch on March 11, the day that the WHO acknowledged that the spread of COVID-19 was a pandemic. The trailer will point to the web page that has been created, and includes the full recording: https://fnih.org/what-we-do/programs/quiet-leaders-covid-shaping-future-science.	Funded from the Pandemic Response Fund	Jul-21
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).	In Q4 2021, the 9th annual Lurie Prize in Biomedical Sciences winner, Xiaowei Zhuang, Ph.D., was honored as part of the virtual 2021 FNIH Awards Ceremony.	$1,000,000	Nov-11

Memorials, Awards and Events				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
The Robert and Emily Wurtz Fund to Support Neuroscience Initiatives	The Robert and Emily Wurtz Fund to Support Neuroscience Initiatives will use its funds to support neuroscience initiatives; for example, lectures and awards at the NEI.	In Q4 2021, the FNIH received funds and began working with the donor to establish the Robert and Emily Wurtz Fund to Support Neuroscience Initiatives.	$50,000	TBD
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.	In Q4 2021, the FNIH held a virtual engagement in which the Lurie Prize in Biomedical Sciences, Trailblazer Prize for Clinician- Scientists, and Charles A. Sanders, M.D., Partnership Award were presented.	$352,300	TBD
2022 FNIH Award Ceremony	In 2022 FNIH will hold its tenth annual award ceremony at which it will present the Lurie Prize in Biomedical Sciences	In Q4 2021, the FNIH initiated planning for the 2022 FNIH Award Ceremony.	Fundraising efforts are underway.	TBD

Fellowships and Training				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(Anticipated) Launch Date**
Alter Fund	The Alter Fund aims to develop a lecture series at NIH.	In Q4 2021, FNIH and NIH leadership spoke with Dr. Harvey Alter regarding the direction of the Alter Fund.	$25,100	TBD
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").	In Q4 2021, FNIH staff and leadership continued to discuss the objectives and format of the Notkins NIH lecture or convening.	$1,200,000	Jun-18
Endowments				
Project Name	**Description**	**Latest News**	**Money Raised as of Dec 31, 2021**	**(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.	In Q4 2021, the 23rd annual Salzman Memorial Symposium and Award took place on November 8, 2021, with keynote speaker Professor Kanta Subbarao.	$238,463	Jan-99

New Projects
Closed Projects

Numbers are unaudited and subject to change.

Tab Five
Donors Report

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

2021 Individual Donors by Program Supported

2021 FNIH Award Ceremony

Robert Balthaser and Ricardo C. Araneda, Ph.D.	$500.00
James H. Donovan	$10,000.00
James M. Felser, M.D.	$500.00
Drs. Maria & Ernesto Freire	$3,000.00
Ronald L. Krall, M.D. and Susan J. Krall	$1,000.00
Julie Bell Lindsay In memory of T. Douglas Lindsay	$10,000.00
Edison T. Liu, M.D., Ph.D. and Margaret B. Liu	$1,000.00
Mr. and Mrs. Paul M. Montrone	$25,000.00
Gilbert S. Omenn, M.D., Ph.D. and Martha A. Darling	$10,000.00
Steven and Jann Paul	$5,000.00
Johng S. Rhim, M.D.	$500.00
Dame Jillian Sackler	$10,000.00
Fred A. and Donna Seigel	$75,000.00
Solomon H. Snyder, M.D.	$7,000.00
Nina K. Solarz	$2,000.00
Russell W. Steenberg and Patricia Colbert	$10,000.00
Paul Stoffels, M.D. and Katelijne Bruurs	$10,000.00
Harold E. Varmus, M.D.	$300.00
Mary Woolley	$500.00

Abrams Charitable Fund

The Jeffrey A. Abrams and Rosalyn L. Abrams Charitable Trust	$14,200.00

Adam J. Berry Memorial Fund

Joseph N. and Michie Flanz	$500.00
Henry L. Hecht	$3,500.00
Lori A. Rolnick	$300.00
Dr. Stuart H. Yuspa and Eleanor H. Yuspa	$500.00

Alter Fund

Harvey J. Alter, M.D. and Diane Dowling, Ph.D.	$20,000.00

Alzheimer's Disease Neuroimaging Initiative 3

Jeffrey Chow	$375.00
John M. Mulhern	$54.34
Mary Anne Schofield	$5,000.00

AMP - Parkinson's Disease

Christopher and Elise Gladstone	$10,000.00
John M. Mulhern	$53.33

AMP - Alzheimer's Disease 2.0

Charles J. and Connie Bocklet	$1,000.00
Kandis Cooke	$250.00

Elinore Eschmann	$250.00
Andrew Kraus	$250.00
Kevin and Caroline Vaughn	$500.00

BC - Membership

Arlene L. Feit	$360.00

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

Jeffrey Chow	$375.00
John Madden, Jr.	$1,000.00
Mary Anne Schofield	$1,000.00
Mr. Mehdi Nafissi and Dr. Ann F. Welton	$500.00
Joel Yesley	$400.00

BRCA Challenge Fund

Andrew and Elyse Steinhaus	$5,562.64

Cancer Research Fund

Jeffrey Chow	$375.00
John M. Mulhern	$222.33
Matthew Scher and Barbara Lazio	$5,000.00

CarMollNat Muscular Dystrophy Endowment

Carol-Ann Harris	$11,397.00

Charles A. Sanders Legacy Fund - Project Legacy

John and Sandra Atkins	$1,000.00

Dean R. O'Neill Renal Cell Cancer Research Fund

Margaret Gavin	$262.50
Michael and Nancy Kelly	$262.50
Chris Themak	$420.00

Deeda Blair Research Initiative Fund for Disorders of the Brain

Margaret Blair	$500.00
Mrs. William McCormick Blair, Jr.	$96,937.58
Buffy and William Cafritz Family Foundation	$5,000.00
William W. Crouse	$20,000.00
Terence F. Eagleton	$2,000.00
John and Margot Ernst	$10,000.00
Cathy Graham	$15,000.00
Alan W. Kornberg and Harold Koda	$5,000.00
William and Stephanie Marra	$250.00
Michael Jefferson Meagher	$25,000.00
Caroline R. Milbank	$1,000.00
Deborah Nevins	$500.00
Mary Kathryn Norman-Navab	$25,000.00

Elizabeth Peabody	$5,000.00
Renvy Graves Pittman	$25,000.00

Dr. Jane M. Sayer Vision Research Lecture & Award

Jane M. Sayer, Ph.D.	$40,000.00

Edmond J. Safra Lodge-All Programs

Anonymous	$20.00
Dr. and Mrs. James E. Balow, M.D.	$700.00
David J. Bouman	$1,000.00
Gene and Esther Gorman	$1,300.00
David and Marijean Hahn	$250.00
Chris and Laura C. Hazzard	$850.00
Patricia S. Kohlen	$14,362.78
Berit Lund	$250.00
Gretchen Naylor	$250.00
Matt and Robyn Nichols Painter	$1,000.00
The Relias Family	$500.00
Johng S. Rhim, M.D.	$500.00
Barbara Santos	$2,700.00
Joseph Scardapane	$250.00
Joann Spence	$1,000.00
Daniel M. Voorhees	$1,000.00
Vincenzo Zitarosa	$250.00

Follicular Lymphoma Research Fund

Steve and Chris Wilsey	$5,000.00

Futures Fund

Steven and Jann Paul	$2,367.50

James T. Wendel Fund

Estate of James T. Wendel	$1,572,600.56

John and Elaine Gallin Fund

Robert L. and Janice Diamond	$10,000.00

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

Eric J. and Susan Hatch	$300.00
William Morley and Caroline Trahan	$2,000.00

Lurie Prize

Ann Lurie	$100,000.00

Medical Research Scholars Program

Buffy and William Cafritz Family Foundation	$30,000.00
Michael M. Kaback, M.D.	$500.00

Norman P. Salzman Memorial Fund

Lenore R. Salzman	$2,500.00

Pamela Anne Cafritz Renal Cell Carcinoma Award Fund

Buffy and William Cafritz Family Foundation	$100,000.00

Pandemic Response Fund

Robert and Jayne Abshire	$500.00
Anonymous	$217.50
James Simpson	$250.00
Samuel O. Thier, M.D. and Paula Thier	$500.00

Piatigorsky Basic Science Lecture and Award

Dr. and Mrs. Joram Piatigorsky	$300,000.00

Robert H. Wurtz Fund to Support Neuroscience Initiatives

Dr. and Mrs. Robert H. Wurtz	$50,000.00

Robert Whitney Newcomb Memorial Fund

Bob and Sally Newcomb	$39,528.60

Solarz Memorial Fund

Alex P. and Drew E. Burrows	$250.00
Keith F. and Alison Burrows	$700.00
Donald Burrows	$1,000.00
Carol Ertel	$500.00
Daniel H. Ertel	$500.00
Randy K. Glantz	$9,000.00
Margaret Grieve	$2,000.00
Eric Hirschhorn and Leah Wortham	$1,000.00
Howard H. and Jacqueline K. Levine	$1,180.00
The Honorable and Mrs. Matthew McHugh	$500.00
Nina K. Solarz	$10,000.00

Stephen E. Straus Distinguished Lecture in CAM

James M. Felser, M.D.	$725.17

Temporarily Restricted

Douglas Albright	$1,500.00
Kenny and Peri Boersema	$325.00
Michelle Borrus	$360.00
Dr. Francis Collins and Diane Baker	$500.00
Annette L. Nazareth and Roger W. Ferguson, Jr.	$25,000.00
Francesca Fleischer	$5,000.00
Lorene Steinberg	$500.00
Richard and Nadine Woldenberg	$5,000.00

Unrestricted

Jonathan Abney	$300.00
Dr. James S. Alexander	$500.00
Stephen and Sharon Alpert	$300.00
Ruwan Alwis	$250.00
Jeffrey D. and Ann Anderson	$1,000.00
Anonymous	$63,192.16
John and Sandra Atkins	$500.00
William Aughenbaugh	$1,000.00
Dr. Nadarajah Balasubramanian	$1,000.00
Robert Balthaser and Ricardo C. Araneda, Ph.D.	$1,300.00
Barbara Basden	$500.00
Sheila Bassett	$300.00
Joan Beck	$250.00
Ronald and Barbara Berke	$2,500.00
Albert M. Bernath, Jr., M.D.	$250.00
John Bertschy	$5,000.00
Lori Bettinger	$1,000.00
Jon H. Beusen and Denise D. Beusen, Ph.D.	$1,375.00
James K. and Deborah M. Bieging	$500.00
Will and Berta Blades	$350.00
Mrs. William McCormick Blair, Jr.	$500.00
Zachary T. Bloomgarden, Ph.D. and Kathy F. Bloomgarden, Ph.D.	$2,000.00
Paula L. and William C. Bradley	$500.00
Marc and Debbie Breslawsky	$1,000.00
Nancy G. Brinker	$3,000.00
Manson K. Brown	$250.00
John S. Buchignani, M.D.	$250.00
Louis Maximilian Buja, M.D.	$450.00
Raymond and Bonnie Carlson	$250.00
Dan Balliet and Jan Carlson	$1,500.00
Gina D. Chalmers	$1,000.00
Lan Chang, M.D.	$500.00
Lloyd Shorter and Jolly Clarkson-Shorter	$250.00
Rochelle S. Cohen	$500.00
John F. Malmros and Rosemary F. Contin	$500.00
Martin J. Corso, M.D.	$300.00
Ralph H. and Karen K. Craft	$6,000.00
Stewart A. Daniels, M.D.	$1,000.00
B.A. Dass	$600.00
Paul J. Davis, M.D.	$1,000.00
Dr. and Mrs. Marijn Dekkers	$2,000.00
Jeff J. Doenges	$300.00
Mark C. Donaldson	$250.00
James H. Donovan	$50,000.00
Ronald Early	$500.00

Dr. Roland D. Eavey and Dr. M.S. Desmond	$500.00
Drs. Howard J. Eisen and Judith E. Wolf	$500.00
Alicia Emerson	$1,000.00
William and Renee Enright	$250.00
Richard W. Erbe, M.D.	$500.00
Margaret J. Erhart	$1,000.00
Ronald G. Evens, M.D.	$1,000.00
Faye Fager	$500.00
Susan E. Finley	$1,000.00
Jeffrey and Marilyn Finn	$900.00
We Chen Foo	$300.00
Daniel M. Freeman Mimi Legat	$5,000.00
Drs. Maria & Ernesto Freire	$3,500.00
Laren Friedman	$600.00
Ruth Friedman	$2,000.00
Thomas Gasparini	$300.00
James and Karen Gavic	$2,000.00
Martin Gellert, Ph.D.	$250.00
Keith Gendler	$1,020.00
Dr. Rona G. Giffard, M.D.	$500.00
Barry H. Ginsberg, M.D., Ph.D.	$500.00
Theodore N. Giovanis, M.B.A.	$5,000.00
Leonard M. and Cynthia A. Glassman	$1,000.00
Randall and Holly Griffin	$750.00
Stacy F. Harrison	$500.00
Gregory and Sally Henderson	$250.00
Stephen and Teri Herbst	$500.00
Dr. and Mrs. Paul L. Herrling	$1,000.00
William E. and Louise A. Hess	$500.00
Donald Hill and Carolyn Ross	$250.00
Willard Hillegeist	$250.00
Susan C. Horowitz	$500.00
John L. and Mary Emma C. Hoye	$504.00
Luanne Hudson	$500.00
Andrew Huff	$250.00
David R. Inman	$300.00
Dr. and Mrs. Thomas R. Insel	$10,000.00
Stephanie L. James, Ph.D.	$750.00
Laura Jansen	$1,000.00
James F. and Gudrun Jeffrey	$500.00
Robert S. and Raissa H. Johnson	$400.00
Richard Jonas and Katherine Vernot-Jonas	$1,000.00
Douglas M. and Lynn C. Klock	$1,000.00
Teresa and Kevin A. Klock	$3,000.00
Mark and Cathy Knepper	$250.00
Dr. Louis Y. Korman	$1,200.00

Ronald L. Krall, M.D. and Susan J. Krall	$500.00
Jeremy Krasner	$1,000.00
Rich Krauzlis	$250.00
Lisa Kuzel	$3,000.00
Arnold Lakind	$500.00
John Larabee	$600.00
Aleah Laxton	$432.25
Philip and Nancy N. Lee	$1,000.00
Ann Lemmon	$3,000.00
Janelle Lewis	$600.00
Cheryl Liechty	$500.00
Dr. and Mrs. Lewis A. Lipsitz	$250.00
Dongxin Luo	$252.00
Nancy R. Madden	$500.00
Leonard and Karen Madoff	$300.00
Paul D. Manca, J.D.	$2,000.00
Anne Alexander Marshall, Ph.D. and Davis Marshall	$250.00
Cathleen Martin	$500.00
John and Stacy Martin	$1,000.00
Catherine Master	$500.00
Steve and Sherry Mayer	$10,000.00
Charles McCormick	$500.00
Judi McCormick	$500.00
Randall McEntire	$250.00
Laurence McMillan	$735.00
Cheryl L. Melencio	$170.00
Ari and Abbey Meltzer	$500.00
Joseph Menetski, Ph.D.	$1,200.00
Raymond Michael	$1,000.00
Judith Miller	$300.00
Mr. and Mrs. Paul M. Montrone	$50,000.00
John M. Morrow	$1,000.00
Morton L. Moss, M.D.	$250.00
Jonathan R. Oates	$600.00
Paul and Cindy Obermeyer	$2,400.00
Mariann O'Brien	$960.00
Gilbert S. Omenn, M.D., Ph.D. and Martha A. Darling	$25,000.00
Sheela Pai Cole	$1,000.00
Sarah Palamara	$2,000.00
Farhan Panthaki	$500.00
Edmund and Megan Pantuliano	$1,000.00
Brian Park	$1,200.00
Kunal Patel	$2,500.00
Dr. Sapna Patel	$2,500.00
Steven and Jann Paul	$10,000.00
Jeffrey Peterson	$1,000.00
Marshall and Kathy Peterson	$300.00

Mr. and Mrs. Stephen Peth	$1,500.00
Rebecca Phinney	$1,000.00
Eric F. Polhamus	$1,000.00
Jan and William Price	$800.00
Helen R. Quill, Ph.D.	$500.00
Sunny Raspet	$5,000.00
Jacqueline Ratner	$250.00
Kathleen M. Reardon	$500.00
Kimberly Rhodes	$250.00
Glen Richards	$500.00
Michael J. Richman	$250.00
Joel and Barbara Richmon	$500.00
Andrew Rohr	$20,000.00
Robert A. and Marjorie Rosenberg	$1,000.00
Jennifer Rosenbluth-Stoll and Peter Stoll	$600.00
Sidney Rosenzweig	$250.00
Rosemary Rosso	$1,000.00
Dame Jillian Sackler	$10,000.00
Mrs. Lily Safra	$50,000.00
John Salvino	$500.00
Charles A. Sanders, M.D. and Ann E. Sanders	$10,000.00
Michael Santos, Ph.D.	$600.00
Dr. Pirmin Schmid	$1,182.17
Darren Schneider	$300.00
Dr. and Mrs. George Schneider	$250.00
Elizabeth K. Schodek	$1,000.00
Benjamin A. Schwartz	$500.00
Edward A. Seidel, M.D.	$1,000.00
Fred A. and Donna Seigel	$10,000.00
Norman E. Sharpless, M.D.and Julie Sharpless, M.D.	$1,000.00
Dr. John N. Sheagren	$500.00
Robert B. and Tammy Renee Sher	$500.00
Daniel R. Shively	$500.00
Steven L. and Karin Siegel	$5,000.00
Richard I. and Anastasia Smith	$1,000.00
Solomon H. Snyder, M.D.	$7,000.00
Drs. Thomas A. Steitz and Joan A. Steitz	$500.00
Jamie Stern	$500.00
Tony and Meredith Stern	$2,500.00
Paul Stoffels, M.D. and Katelijne Bruurs	$25,000.00
Rainer F. Storb, M.D.	$375.00
Suresh and Feroza Subramani	$300.00
Michael Sullivan	$250.00
Joseph G. Perpich, M.D., J.D. and Cathy J. Sulzberger	$1,500.00
Anthony Tassone	$250.00
Christopher A. and Elizabeth Thoma	$850.00
William, Zani and Aycen Tolentino	$10.00

Anne S. Tsukuda	$1,500.00
Meredith Upton	$250.00
David Van Hemel	$800.00
Jon and Kristin Vaver	$1,000.00
Andrew Veale	$750.00
Ellyn S. Wagner	$750.00
Paula J. Warrick, Ph.D.	$720.00
Robert C. Watson and Debra D. Petersen	$300.00
Susan Wechsler	$500.00
Marjorie Weiner	$250.00
Roger Weisman	$1,000.00
Theodore and Katherine Wells	$500.00
Sara Lou Whildin	$2,500.00
David Wholley	$2,500.00
Ingrid Wiley	$250.00
Stewart K. Wilson	$1,000.00
Dyann Wirth	$250.00
Julie and Howard Wolf-Rodda	$600.00
Julie and Howard Wolf-Rodda	$600.00
Martin Wolk	$970.30
Richard G. Wyatt, M.D. and Linda S. Wyatt, Ph.D.	$3,000.00
Jay Yarington	$250.00
Lucas and Katrina Yun-Nikolac	$499.28
Daniel Zhao	$1,000.00

2021 Organizational Donors by Program Supported

2021 FNIH Award Ceremony

Aegis Sciences Corporation	$2,000.00
Biogen	$10,000.00
Braidwell Management Company LP	$10,000.00
Cerevel Therapeutics	$10,000.00
City of Hope	$500.00
Ginkgo Bioworks	$2,000.00
Goulston & Storrs PC	$10,000.00
Horizon Therapeutics plc	$2,000.00
Joseph Gawler's Sons, LLC	$500.00
Eli Lilly and Company	$10,000.00
Meridian Bioscience	$10,000.00
Morgan Stanley & Co. Incorporated	$10,000.00
National Rongxiang Xu Foundation	$5,000.00
NEWMARK	$10,000.00
Novalis LifeSciences LLC	$50,000.00
Omega World Travel Inc.	$2,000.00
Polaris Partners	$10,000.00
Quanterix	$10,000.00
Truist	$2,000.00
Vizgen	$5,000.00

Accelerating COVID-19 Therapeutic Interventions and Vaccines

National Institutes of Health	$4,395,399.00

ADNI - Amyloid PET Early Frames Add on Study

Johnson & Johnson	$50,000.00

Alzheimer's Disease Neuroimaging Initiative 3

Araclon Biotech, S.L.	$10,000.00
FUJIFILM Toyama Chemical Co., Ltd.	$25,000.00
Hewlett Packard Enterprise	$375.00
Invicro	$16,666.00
IXICO	$16,666.00
Eli Lilly and Company	$150,000.00
Saladax Biomedical, Inc.	$10,000.00

Amgen Scholars Program

Amgen Foundation	$167,500.00

AMP - Parkinson's Disease

The Geaton & JoAnn DeCesaris Family Foundation, Inc.	$15,000.00

AMP - Alzheimer's Disease 2.0

Eisai Inc.	$2,690,000.00
Gates Ventures	$2,690,000.00

AMP - Autoimmune and Immune-Mediated Diseases (AMP AIM)

AbbVie Inc.	$2,250,000.00
Bristol Myers Squibb	$2,250,000.00
GlaxoSmithKline	$2,250,000.00
Johnson & Johnson	$2,250,000.00
Lupus Foundation of America	$15,000.00
Lupus Research Alliance	$300,000.00
National Psoriasis Foundation	$100,000.00
Novartis Pharmaceuticals Corporation	$2,250,000.00
Pfizer Inc.	$2,250,000.00
Sanofi	$1,910,400.00
Sjögren's Foundation, Inc.	$300,000.00
UCB, Inc.	$2,250,000.00

AMP - Common Metabolic Diseases (AMP-CMD)

Amgen Inc.	$1,700,000.00
Novo Nordisk A/S	$1,700,000.00
Pfizer Inc.	$1,360,400.00

AMP - Gene Therapy Implementation Phase (BGTC)

Alliance for Regenerative Medicine	$75,000.00
American Society of Gene & Cell Therapy	$75,000.00
Biogen	$3,000,000.00
CureDuchenne	$300,000.00
Johnson & Johnson	$3,000,000.00
National Organization for Rare Disorders (NORD)	$300,000.00
Novartis Pharmaceuticals Corporation	$3,000,000.00
Pfizer Inc.	$3,000,000.00
REGENXBIO Inc.	$450,000.00
Rett Syndrome Research Trust	$75,000.00
Spark Therapeutics, Inc.	$900,000.00
Takeda Pharmaceutical Company Limited	$3,000,000.00
Taysha Gene Therapies	$300,000.00
Thermo Fisher Scientific Inc.	$750,000.00
Ultragenyx Pharmaceutical	$1,050,000.00
University of Delaware	$100,000.00

AMP - Heart Failure Design Phase

Abbott	$20,000.00
AstraZeneca Pharmaceuticals LP	$20,000.00
Eli Lilly and Company	$20,000.00
MyoKardia	$20,000.00

AMP - Schizophrenia

Schizophrenia & Psychosis Action Alliance	$300,000.00
Wellcome	$2,927,527.26

BC - 2021 Cancer Steering Committee Annual Scientific Symposium

Adaptive Biotechnologies Corporation	$25,000.00
Alkermes, Inc.	$5,000.00
GenMab US, Inc.	$5,000.00
Ikena Oncology	$10,000.00
Johnson & Johnson	$10,000.00
PathAI, Inc.	$5,000.00

Pfizer Inc.	$25,000.00
Regeneron Pharmaceuticals, Inc.	$5,000.00
Sengenics Corporation	$5,000.00
Society for Immunotherapy of Cancer	$2,500.00
Takeda Pharmaceutical Company Limited	$5,000.00

BC - A Novel Total Lesional Automated Computerized Imaging Platform, Biomarker, and Predictive Model

Johnson & Johnson	$100,000.00

BC - Chemotherapeutic Impact on the Immune MicroEnvironment (CHIIME)

EMD Serono, Inc.	$150,000.00
Merck Sharp & Dohme LLC	$1,100,000.00

BC - ctDNA Reference Material

AstraZeneca Pharmaceuticals LP	$103,215.00
Genentech, Inc.	$103,215.00
Johnson & Johnson	$103,215.00
Merck Sharp & Dohme LLC	$103,215.00
PerkinElmer Inc.	$104,516.40
Pfizer Inc.	$77,411.00

BC - Early Detection of Preeclampsia

Thermo Fisher Scientific Inc.	$360,000.00

BC - Measurable Residual Disease - Acute Myeloid Leukemia

Amgen Inc.	$187,500.00
AstraZeneca Pharmaceuticals LP	$187,500.00
Genentech, Inc.	$130,000.00
GlaxoSmithKline	$187,500.00
Novartis Pharmaceuticals Corporation	$187,500.00
Sysmex Inostics	$187,500.00

BC - Membership

Adaptive Biotechnologies Corporation	$20,000.00
ADx NeuroSciences	$10,000.00
Alkermes, Inc.	$30,000.00
Amgen Inc.	$300,000.00
AMRA Medical	$10,000.00
The Association for Frontotemporal Degeneration	$5,000.00
Association for Molecular Pathology	$5,000.00
Astellas Pharma Inc.	$28,000.00
AstraZeneca Pharmaceuticals LP	$80,000.00
Bayer AG	$120,000.00
Bio-Rad Digital Biology Group	$30,000.00
Boehringer Ingelheim Pharmaceuticals, Inc.	$40,000.00
BrightFocus Foundation	$5,000.00
Bristol Myers Squibb	$80,000.00
C2N Diagnostics	$10,000.00
CHDI Foundation	$13,500.00
Clario	$10,000.00
Cognition Therapeutics, Inc.	$10,000.00
Frederick National Laboratory for Cancer Research	$5,000.00
Gates Ventures	$15,000.00
Genentech, Inc.	$120,000.00

Genmab A/S	$15,000.00
GlaxoSmithKline	$405,000.00
Ikena Oncology	$10,000.00
Invicro	$10,000.00
Johnson & Johnson	$150,000.00
Laboratory Corporation of America	$10,000.00
Eli Lilly and Company	$150,000.00
Merck Sharp & Dohme LLC	$110,400.00
The Multiple Myeloma Research Foundation	$5,000.00
Neurimmune AG	$10,000.00
Novartis Pharmaceuticals Corporation	$40,000.00
Olink Proteomics	$10,000.00
Pharmaceutical Research and Manufacturers of America	$50,000.00
Radiological Society of North America	$5,000.00
Radiomics	$27,000.00
Regeneron Pharmaceuticals, Inc.	$150,000.00
Sage Therapeutics	$15,000.00
Sanofi	$150,000.00
Seagen, Inc.	$15,000.00
Sengenics Corporation	$10,000.00
Sjögren's Foundation	$5,000.00
UCB, Inc.	$56,000.00
Verily	$10,000.00

BC - Mucosal Healing in Ulcerative Colitis

Crohn's and Colitis Foundation	$33,333.00

BC - Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration in Familial Frontotemporal Degeneration

Alector, Inc.	$140,000.00
The ALS Association	$140,000.00
The Association for Frontotemporal Degeneration	$84,388.00
Alzheimer's Drug Discovery Foundation	$250,000.00
The Bluefield Project to Cure Frontotemporal Dementia	$32,534.00
Otsuka Pharmaceutical Co., Ltd.	$560,000.00
Rainwater Charitable Foundation	$70,000.00

BC - Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE)

Allergan, Inc.	$478,824.00
Amgen Inc.	$1,078,824.00
AstraZeneca Pharmaceuticals LP	$478,824.00
Boehringer Ingelheim Pharmaceuticals, Inc.	$478,824.00
Bristol Myers Squibb	$478,824.00
Canon Medical Systems USA, Inc.	$555,000.00
Echosens SA	$877,272.00
GE Healthcare	$756,024.00
Genentech, Inc.	$478,824.00
Genfit	$350,000.00
Gilead Sciences, Inc.	$478,824.00
Intercept Pharmaceuticals, Inc.	$578,824.00
Nordic Bioscience A/S	$944,000.00
Novo Nordisk A/S	$478,824.00
OWL Metabolomics	$354,000.00
Pfizer Inc.	$478,824.00
Philips Healthcare	$70,000.00

Regeneron Pharmaceuticals, Inc.	$1,078,824.00
Siemens	$536,000.00
SuperSonic Imagine	$70,000.00
Takeda Pharmaceutical Company Limited	$478,824.00

BC - Plasma Aß as a Predictor of Amyloid Positivity in Alzheimer's Disease

AbbVie Inc.	$201,000.00
Alzheimer's Association ®	$196,716.50
Alzheimer's Drug Discovery Foundation	$201,000.00
Biogen	$201,000.00
Johnson & Johnson	$201,000.00
Takeda Pharmaceutical Company Limited	$201,000.00

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

Alkermes, Inc.	$450,000.00
Alzheimer's Drug Discovery Foundation	$300,000.00
Biogen	$450,000.00
Genentech, Inc.	$450,000.00
Hewlett Packard Enterprise	$375.00
Johnson & Johnson	$627,835.00
Johnson & Johnson Family of Companies Matching Gift Program	$500.00
Sage Therapeutics	$450,000.00
Takeda Pharmaceutical Company Limited	$627,335.00
Arthritis Foundation	$200,000.00
EMD Serono, Inc.	$100,000.00
Pfizer Inc.	$100,000.00

Cancer Research Fund

Estate of Jean Lough Heagy	$52,234.81
Hewlett Packard Enterprise	$375.00

Comprehensive Cellular Vaccine Immune Monitoring Consortium (CCVIMC.2.0)

Bill & Melinda Gates Foundation	$5,726,937.00

Dean R. O'Neill Renal Cell Cancer Research Fund

The Pittsburgh Foundation	$532.24

Deeda Blair Research Initiative Fund for Disorders of the Brain

The Nicholls Biondi Foundation	$50,000.00

Edmond J. Safra Lodge

Ergonomic Group Inc	$500.00
Lafayette 89	$500.00
Northrop Grumman Corporation	$260.00

Fifth Annual Vivian Pinn Symposium

AccessCircles Inc	$5,000.00
American Society for Reproductive Medicine	$5,000.00
Amgen Inc.	$25,000.00
Elsevier, Inc.	$5,000.00
Hologic, Inc.	$25,000.00
Myovant Sciences	$10,000.00
Sanofi	$5,000.00

Gilead HIV Cure Grant Program

Gilead Sciences, Inc.	$765,405.00

Gilead Leidos (Car-T)

Gilead Sciences, Inc.	$445,001.00

Global Collaborative for Coordination of Gene Drive Research and Development

Bill & Melinda Gates Foundation	$3,000,000.00

Gramlich Trust Melanoma Research

Jack Gramlich Foundation	$24,574.00

Helping to End Addiction Long-term Partnership

National Institutes of Health	$42,657.66

Intelligent Sight and Sound

Booz Allen Hamilton Inc.	$29,568.00

JKTG Foundation - Post-Bacc and Graduate Intramural Research Training Fellows

Jayne Koskinas Ted Giovanis Foundation for Health and Policy	$180,600.00

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

Corliss Foundation	$100,000.00
Driven To Cure, Inc.	$100,335.00

Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation

Amgen Inc.	$3,390,871.04
ImmunityBio	$3,103,777.94
Eli Lilly and Company	$651,585.80
Pfizer Inc.	$93,565.00

Medical Research Scholars Program

American Association for Dental Research	$75,000.00
Colgate-Palmolive Company	$37,500.00

Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs

Bill & Melinda Gates Foundation	$3,927,840.00

Pandemic Response Fund

Johnson & Johnson Family of Companies Matching Gift Program	$150.00

Pew Latin American Fellows Awards

The Pew Charitable Trusts	$23,625.00

Pursuant to 42 U.S.C. §290b(l)

National Institutes of Health	$1,250,000.00

Stephen E. Straus Distinguished Lecture in the Science of Complementary Health Therapies

Novartis Pharmaceuticals Corporation	$1,500.00

Temporarily Restricted

Posey-Glickert Foundation	$20,000.00
The Harry and Jeanette Weinberg Foundation, Inc.	$5,000.00

Understanding the Mechanisms of Intravenous BCG-induced Protection Against TB in NHP

Bill & Melinda Gates Foundation	$2,018,529.00

Unrestricted

Abbott	$250.00
Amazon Smile Foundation	$821.38
American Endowment Foundation	$15,000.00
America's Charities	$1,275.99
Apple Inc.	$1,505.00
Ariannie Fund	$2,500.00
Bank of America Matching Gifts Program	$400.00
Cerf-Dunbar Fund	$1,000.00
Drug Safety Navigator	$2,000.00
Estate of Brenda Marie Geist	$136,598.37
F5 Networks	$433.93
Facebook Donors	$4,036.89
Friends of Cancer Research	$10,000.00
Global Impact Combined Federal Campaign	$5,452.55
Google, Inc.	$1,022.00
Hubble Charitable Fund	$1,000.00
International Monetary Fund	$301.00
Jamari Foundation	$1,000.00
Johnson & Johnson	$150.00
Kenneth and Rhoda Herman Foundation	$2,000.00
Judy and Peter Blum Kovler Foundation	$26,000.00
Malek Family Charitable Trust	$500.00
Pfizer Foundation Matching Gifts Program	$1,000.00
Premier Inc	$500.00
Ruder & Finn, Inc.	$1,000.00
StudiGo LLC	$500.00
Suncor Energy	$432.20
Technomics Research	$2,700.00
The Bigger Family Foundation	$250.00
The Nederlander Organization	$1,000.00
The Richard H. Yearick Foundation	$10,000.00
Tischfield Family Charitable Gift Fund	$300.00
Todd Wagner Foundation	$10,000.00
University of Pennsylvania	$3,022.59
Wiley Rein LLP	$500.00
Wolk Family Fund	$2,500.00
Zerhouni Family Charitable Foundation, Inc.	$15,000.00

Using Biomarkers to Predict TB Treatment Duration

Bill & Melinda Gates Foundation	$956,860.00

Foundation for the
National Institutes of Health

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
Foundation for the
National Institutes of Health

Foundation for the
National Institutes of Health

Allocation of NIH Support to the FNIH

FY2022

Office Space	$ 600,000
New Staff*	587,500
Unrecovered Program Expenses	45,000
Obtained Cyber Insurance Coverage	17,500
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 have been no pandemic-related staff cuts.

Tab Seven

Financial Statements and Report of the Independent Auditors

FNIH
Foundation for the National Institutes of Health

Foundation for the National Institutes of Health, Inc.

Financial Statements

Years Ended December 31, 2021 and 2020

DHG

Table of Contents

DHG

Independent Auditors' Report

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

Report on the Audit of the Financial Statements

Opinion
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, 2021 and 2020, and the related statements of activities, functional expenses and cash flows for the years then ended, and the related notes to the financial statements.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of Foundation for the National Institutes of Health, Inc. as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion
We conducted our audits in accordance with auditing standards generally accepted in the United States of America (GAAS) and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Our responsibilities under those standards are further described in the Auditors' Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of Foundation for the National Institutes of Health, Inc. and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of Management for the Financial Statements
Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for 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.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about Foundation for the National Institutes of Health, Inc.'s ability to continue as a going concern for one year after the date that the financial statements are available to be issued.

Auditors' Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not absolute assurance, and therefore is not a guarantee that an audit conducted in accordance with GAAS and *Government Auditing Standards* will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS and *Government Auditing Standards*, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit 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 Foundation for the National Institutes of Health, Inc.'s internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about Foundation for the National Institutes of Health, Inc.'s ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

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 33, 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 6, 2022, 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 6, 2022

Foundation for the National Institutes of Health, Inc.
Statements of Financial Position
December 31, 2021 and 2020

	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 39,815,103**	$ 62,837,436
NIH receivable	**500,000**	500,000
Contributions receivable, net, current portion	**43,332,234**	21,032,937
Accrued interest	**126,005**	175,575
ERC grant receivable	**347,757**	350,943
Prepaid expenses and other receivables	**3,091,847**	1,982,460
Total current assets	**87,212,946**	86,879,351
Contributions receivable, net, less current portion	**23,293,459**	19,825,974
Investments	**109,707,585**	63,285,583
Property and equipment, net	**1,725,769**	1,948,833
Total assets	**$ 221,939,759**	$ 171,939,741
LIABILITIES AND NET ASSETS		
Current liabilities:		
Accounts payable and accrued expenses	**$ 8,537,356**	$ 7,166,950
Charitable gift annuity	**119,864**	125,764
Total current liabilities	**8,657,220**	7,292,714
Advance receipts on conditional contributions	**338,978**	1,331,478
Deferred lease incentive	**1,408,688**	1,538,721
Deferred rent liability	**585,551**	572,612
Total liabilities	**10,990,437**	10,735,525
Net assets:		
Without donor restrictions:		
Unrestricted, general	**5,253,326**	6,216,465
Board designated	**23,290,885**	19,152,000
Total without donor restrictions	**28,544,211**	25,368,465
With donor restrictions	**182,405,111**	135,835,751
Total net assets	**210,949,322**	161,204,216
Total liabilities and net assets	**$ 221,939,759**	$ 171,939,741

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Activities
Year Ended December 31, 2021

	Without Donor Restrictions	With Donor Restrictions	Total
Revenue, support and other changes:			
Contributions	$ 829,206	$ 99,237,554	$ 100,066,760
Grants	43,744	-	43,744
In-kind contributions	3,936,832	-	3,936,832
Transfers from NIH	1,250,000	-	1,250,000
Donated services	16,900	-	16,900
Fundraising event	352,300	-	352,300
Investment and interest income, net	1,149,891	732,550	1,882,441
ERC grant income	913,617	-	913,617
Administrative revenue	50,000	-	50,000
Net assets released from restrictions:			
Satisfaction of indirect cost requirements	5,415,213	(5,415,213)	-
Satisfaction of program restrictions	47,985,531	(47,985,531)	-
Total revenue, support and other changes	61,943,234	46,569,360	108,512,594
Expenses:			
Program services:			
Fellowships and training programs	852,431	-	852,431
Memorials, awards and events	457,912	-	457,912
Capital projects	53,512	-	53,512
Research programs	50,719,285	-	50,719,285
Total program services	52,083,140	-	52,083,140
Supporting services:			
Management and general	6,310,346	-	6,310,346
Fundraising	374,002	-	374,002
Total supporting services	6,684,348	-	6,684,348
Total expenses	58,767,488	-	58,767,488
Change in net assets	3,175,746	46,569,360	49,745,106
Net assets, beginning of year	25,368,465	135,835,751	161,204,216
Net assets, end of year	$ 28,544,211	$ 182,405,111	$ 210,949,322

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
ERC grant income	350,943	-	350,943
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	63,489,147	38,903,435	102,392,582
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	6,609,054	-	6,609,054
Fundraising	437,019	-	437,019
Total supporting services	7,046,073	-	7,046,073
Total expenses	59,698,656	-	59,698,656
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 Functional Expenses
Year Ended December 31, 2021

	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	$ 23,559	$ 105,256	$ 16,467	$ 6,671,516	$ 6,816,798	$ 4,311,095	$ 173,609	$ 4,484,704	$ 11,301,502
Stipends	-	105,500	10,000	-	115,500	-	20,000	20,000	135,500
Programs contracts	816,045	192,000	-	33,633,818	34,641,863	12,480	-	12,480	34,654,343
Grant awards	-	-	-	5,287,365	5,287,365	-	-	-	5,287,365
Meetings and travel	2,513	14,397	23,262	94,229	134,401	5,989	81,979	87,968	222,369
Office supplies and expense	4,729	-	1,142	-	5,871	4,597	26	4,623	10,494
Telephone	-	-	-	92,778	92,778	90,229	7,944	98,173	190,951
Books and supplies	323	-	-	13,430	13,753	2,719	-	2,719	16,472
Tuition	-	-	-	5,853	5,853	1,514	-	1,514	7,367
Insurance	-	-	-	135,102	135,102	92,930	-	92,930	228,032
Consultants	-	36,290	175	4,275,240	4,311,705	326,029	18,487	344,516	4,656,221
Professional fees	-	-	-	87,892	87,892	119,089	-	119,089	206,981
Depreciation and amortization	-	-	-	-	-	240,478	-	240,478	240,478
Rent/housing	3,858	-	-	175,724	179,582	567,017	-	567,017	746,599
Recruiting	-	-	-	30,625	30,625	349,134	-	349,134	379,759
Dues and subscriptions	-	-	-	16,879	16,879	14,139	-	14,139	31,018
Equipment and rental and maintenance	585	-	-	3,924	4,509	34,386	-	34,386	38,895
Printing and photocopying	-	-	-	77,693	77,693	93	39,752	39,845	117,538
Postage and delivery	310	15	89	11,311	11,725	5,289	3,086	8,375	20,100
Service charges	292	95	561	3,670	4,618	18,353	941	19,294	23,912
Communication	217	509	-	78,033	78,759	98,295	20,186	118,481	197,240
Advertising and promotion	-	3,850	-	23,963	27,813	5,899	7,059	12,958	40,771
Miscellaneous	-	-	1,816	240	2,056	10,592	933	11,525	13,581
	$ 852,431	$ 457,912	$ 53,512	$ 50,719,285	$ 52,083,140	$ 6,310,346	$ 374,002	$ 6,684,348	$ 58,767,488

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	$ 4,438,334	$ 269,855	$ 4,708,189	$ 11,476,360
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	$ 6,609,054	$ 437,019	$ 7,046,073	$ 59,698,656

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statements of Cash Flows
Years Ended December 31, 2021 and 2020

	2021	2020
Cash flows from operating activities:		
Change in net assets	**$ 49,745,106**	$ 42,693,926
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	**240,478**	250,896
Contributions restricted for long-term purposes	**(16,465)**	(511,998)
Net realized and unrealized gain on investments	**(719,063)**	(1,238,818)
Deferred lease incentive amortization	**(130,033)**	(130,033)
Deferred rent liability	**12,939**	153,064
Change in assets and liabilities:		
Contributions receivable	**(25,766,782)**	(29,404,443)
Accrued interest	**49,570**	378,522
Prepaid expenses and other receivables	**(1,109,387)**	(1,681,824)
ERC grant receivable	**3,186**	(350,943)
Accounts payable and accrued expenses	**1,370,406**	(2,978,743)
Charitable gift annuity	**(5,900)**	(6,027)
Advance receipts on conditional contributions	**(992,500)**	(3,815,884)
Net cash provided by operating activities	**22,681,555**	3,357,695
Cash flows from investing activities:		
Furniture and equipment acquisitions	**(17,414)**	(143,599)
Sales and maturities of investments	**11,955,373**	115,312,812
Purchase of investments	**(57,658,312)**	(85,957,888)
Net cash (used) provided by investing activities	**(45,720,353)**	29,211,325
Cash flows from financing activities:		
Contributions restricted for investment in endowment	**16,465**	511,998
Net (decrease) increase in cash and cash equivalents	**(23,022,333)**	33,081,018
Cash and cash equivalents, beginning of year	**62,837,436**	29,756,418
Cash and cash equivalents, end of year	**$ 39,815,103**	$ 62,837,436
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 and amortization	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 and maintenance	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, 2021 and 2020.

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.

Contributed Nonfinancial Assets

In September 2020, the FASB issued ASU 2020-07, *Presentation and Disclosures by Not-for-Profit Entities for Contributed Nonfinancial Assets*. Under this new standard, nonprofit organizations that receive contributed nonfinancial assets, also known as gifts-in-kind, will be required to provide new presentation on the statement of activities and additional disclosures. Contributed nonfinancial assets will be presented as a separate line item from contributed cash and other financial assets on the statement of activities. Nonprofits will also be required to disclose in a note to the financial statements the amounts of contributed nonfinancial assets by category based on the type of gift with a total that agrees to the amount presented on the statement of activities. Further disclosures to be included in the notes to the financial statements will include the Foundation's policy for monetizing or using these assets, any donor-imposed restrictions on the assets, valuation inputs and techniques used to recognize the assets' initial fair values, and the principal market or most advantageous market used in the fair value measurement of the assets. 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.

Reclassifications

Certain items reported in the prior year financial statements have been reclassified for consistency with the current period presentation. These reclassifications had no effect on net assets or change in net assets.

Subsequent events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 6, 2022, 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:

	2021	2020
Financial assets:		
Cash and cash equivalents	**$ 39,815,103**	$ 62,837,436
NIH receivable	**500,000**	500,000
Contributions receivable, net	**66,625,693**	40,858,911
Other receivables	**3,209,250**	2,097,652
Investments	**109,707,585**	63,285,583
Total financial assets	**219,857,631**	169,579,582
Less amounts not to be used within one year:		
Net assets with donor restrictions	**182,405,111**	135,835,751
Legacy Fund established by the board	**1,604,000**	1,603,000
Quasi endowment established by the board	**18,686,885**	15,549,000
	202,695,996	152,987,751
Financial assets available to meet general expenditures over the next twelve months	**$ 17,161,635**	$ 16,591,831

The Foundation's goal is to maintain financial assets to meet one year of Supporting Services (approximately $8.3 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, 2021 and 2020, 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:

	2021	2020
Furniture and equipment	**$ 1,096,561**	$ 1,079,148
Leasehold improvements	**1,869,159**	1,869,159
	2,965,720	2,948,307
Accumulated depreciation and amortization	**(1,239,951)**	(999,474)
	$ 1,725,769	$ 1,948,833

6. Investments

Investments as of December 31, 2021, are summarized as follows:

	Cost	Market Value
Money market funds	$ 8,177,950	$ 8,177,950
U.S. government bonds	65,044,237	64,776,949
Corporate bonds	14,447,958	14,216,683
Exchange traded funds	4,118,259	5,284,295
Mutual funds	14,515,211	17,251,708
	$ 106,303,615	$ 109,707,585

The following schedule summarizes the investment return and its classification for 2021:

	Without Donor Restrictions	With Donor Restrictions	Total
Interest and dividends	$ 1,093,882	$ 253,000	$ 1,346,882
Realized gain	62,755	114,257	177,012
Unrealized gain	176,758	365,293	542,051
Investment fees	(183,504)	-	(183,504)
Total investment return	$ 1,149,891	$ 732,550	$ 1,882,441

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

7. Contributions Receivable

Contributions receivable at December 31, were as follows:

	2021	2020
Receivable in less than one year	**$ 43,347,234**	$ 21,047,937
Receivable in one to five years	**23,817,562**	20,272,058
Total unconditional contributions receivable	**67,164,796**	41,319,995
Discounts to net present value	**(524,103)**	(446,084)
Allowance for uncollectible contributions receivable	**(15,000)**	(15,000)
Net unconditional contributions receivable	**$ 66,625,693**	$ 40,858,911

The discount rate used on long-term contributions receivable was 2.25% in 2021 and 2020.

8. Conditional Contributions Receivable

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

	2021	2020
Conditioned upon the funder not notifying the Foundation by a specific date that they do not wish to fund the program:		
Using Biomarkers to Predict TB Treatment Duration	**$ -**	$ 956,860
Lurie Prize in Biomedical Research	**-**	100,000
Pew Latin American Fellows Awards	**199,500**	296,625
Efficacy of Heterodimeric IL-15 Treatment Regimens in Reducing SIV Reservoir	**-**	765,405
Conditioned upon meeting certain milestones and/or the funder not cancelling:		
NIH Medical Research Scholars Program	**120,000**	150,000
Alzheimer's Disease Neuroimaging Initiative-3	**-**	228,332
Biomarkers Consortium Treatments Against Rheumatoid Arthritis and Effect on FDG PET-CT	**60,000**	60,000
Amgen NIH Scholars Program	**167,500**	335,000
Pamela Anne Cafritz Renal Cell Carcinoma Award	**-**	100,000
Biomarkers Consortium Osteoarthritis Biomarkers Qualification	**-**	700,000
Biomarkers Consortium Inflammatory Markers for Neurodegenerative and Mood Disorders	**554,500**	554,500
Biomarkers Consortium ctDNA Reference Standards	**-**	490,271
Chemotherapeutic Impact on the Immune MicroEnvironment Project (ChIIME)	**-**	1,250,000
Participation of Native American Students in the National Institute for Neurological Disorders and Stroke (NINDS)	**30,000**	60,000
Non-Invasive BioMarkers of MetaBolic Liver DiseasE (NIMBLE) (Project is not yet launched)	**-**	5,845,888
2020 NINDS SIP	**30,000**	-
Bespoke Gene Therapy Consortium	**12,850,000**	-
Measurable Residual Disease in Multiple Myeloma	**390,000**	-
Understanding NHP protection against TB induced by Intravenous BCG	**381,084**	2,399,613

Accelerating Medicines Partnership: RA, SLE & Related Autoimmune Disorders	**400,000**	-
CAR-T	**111,250**	556,251
ADNI – Amyloid PET Early Frames Add on Study	**-**	50,000
Biomarkers Consortium – Plasma Abeta project	**-**	1,201,717
2019 NINDS/CNS Getch Scholar	**100,000**	100,000
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**2,412,518**	3,499,008
Mucosal Healing in Ulcerative Colitis	**3,436,666**	3,436,665
GeneConvene Global Collaborative	**12,564,694**	15,564,694
Accelerating Medicines Partnership – Schizophrenia	**3,800,000**	3,600,000
NIP- Metastatic Prostate Cancer	**100,000**	200,000
BC-Cachexia	**950,000**	950,000
Joram Piatigorsky Basic Science Lecture and Award	**300,000**	600,000
Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration	**-**	32,534
The Partnership to Accelerate Novel TB Regimens (PAN-TB)	**737,580**	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**	389,908
CCVIMC.2.0	**9,019,856**	-
Biomarkers for Early Detection of Preeclampsia	**140,000**	-
SV2A PET Tracer as a Biomarker for Synaptic Density	**478,788**	-
Accelerating Medicines Partnership - Common Metabolic Diseases (AMP CMD)	**10,200,000**	-
Measurable Residual Disease in Acute Myeloid Leukemia	**3,375,000**	-
Accelerating Medicines Partnership: AIM	**12,810,000**	400,000
	$ 76,108,844	$ 48,838,851

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:

	2021	2020
Endowment Fund	**$ 18,686,885**	$ 15,549,000
Contingency Fund	**3,000,000**	2,000,000
Legacy Fund	**1,604,000**	1,603,000
	$ 23,290,885	$ 19,152,000

10. Net Assets with Donor Restrictions

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

	2021	2020
Fellowships and Training Programs:		
Amgen Scholars Program	**$ 201,729**	$ 150,177
Dean R. O'Neill Renal Cell Cancer Research Fund	**194,136**	192,370
Dr. Edward T. Rancic Memorial Fund	**6,708**	6,705
Dr. John L. Barr Memorial Fund for Cancer Research	**680**	686
Neva Fund	**28,399**	28,388
NIH Medical Research Scholarship Program	**803,238**	1,041,159
NOB Fund	**7,152**	7,152
Norman P. Salzman Memorial Award and Lecture in Virology	**258,599**	234,886
Notkins biomedical Research Fund	**201,811**	201,737
Robert Whitney Newcomb Memorial Lecture and Internship	**1,592,090**	1,422,112
Sallie Rosen Kaplan Fellowship for Women Scientists in Cancer Research	**364,120**	254,328
Swanson Family Fellowship in Generic Thyroid Benign Chorea and IgA Deficiency (TTF-1)	**-**	92,500
Memorials, Awards and Events:		
Adam J. Berry Memorial Fund	**12,802**	8,146
Breast Cancer Summit 2	**65,198**	65,198
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	**312,151**	274,883
Edna Williams Curl & Myron R. Curl Endowment for Multiple Sclerosis Research	**67,395**	67,370
Human Genome Exhibition	**9,245**	9,245
John Laws Decker Memorial Fund	**2,347**	2,346
Joram Piatigorsky Basic Science Lecture and Award	**701,608**	401,380
Kovler Prize for Excellence in Science Journalism	**197,258**	300,507
Lurie Prize	**100,000**	100,000
MRSP 2020-2021	**-**	156,283
MRSP 2021-2022	**119,664**	-
Michael T. Davis Fund	**73,072**	73,072
James T. Wendel Fund	**1,572,601**	-
NINDS/CNSF K12 Scholar Awards Program	**100,000**	195,000
Pamela Ana Cafritz	**100,000**	100,000
Pandemic Response Fund	**252,451**	292,107
Stephen E. Straus Award	**104,944**	104,903
The Robert and Emily Wurtz Fund to Support Neuroscience Init	**50,000**	-
Capital Projects:		
Edmond J. Safra Family Lodge Bricks and Mortar	**79,759**	79,759
Edmond J. Safra Family Lodge All Programs	**50,248**	39,692
Edmond J. Safra Family Lodge GSK Endowment	**757,326**	538,000
Edmond J. Safra Family Lodge Weinberg Endowment	**473,044**	351,512
Edmond J. Safra Family Lodge Gallin Endowment	**104,365**	111,252
Tracy's Toy Box	**7,941**	7,941
Research Partnerships:		
Accelerating Medicines Partnership Membership	**455,365**	460,029
Accelerating Medicines Partnership: Type 2 Diabetes	**-**	3,046,060
Accelerating Medicines Partnership: Alzheimer's	**2,323,224**	2,504,340
Accelerating Medicines Partnership: Alzheimer's Disease 2.0	**12,988,353**	7,943,051
Accelerating Medicines Partnership: AIM	**16,053,279**	100,000
Accelerating Medicines Partnership: Rheumatoid Arthritis and Lupus	**265,389**	1,096,038
Accelerating Medicines Partnership: Parkinson’s Disease	**6,381,076**	7,604,247
Accelerating Medicines Partnership: Schizophrenia	**3,051,180**	5,223,326

Foundation for the National Institutes of Health, Inc.
Notes to Financial Statements

Accelerating Medicines Partnership:		
Common Metabolic Diseases (AMP CMD)	**6,743,993**	1,681,296
ADNI - Amyloid PET Early Frames Add on Study	**716,250**	677,500
Alzheimer's Disease Neuroimaging Initiative – 3	**2,707,081**	2,715,451
AMP - Heart Failure- Design Phase	**190,286**	244,315
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**2,771,029**	65,134
Biomarker Consortium	**5,058,864**	3,935,197
Biomarkers Consortium: Atherosclerosis Computer Modeling	**236,784**	358,639
Biomarkers Consortium: Bone Quality Project	**19,590**	22,230
Biomarkers Consortium: CABP-Skin Infection	**6,657**	19,263
Biomarkers Consortium: HD-SCA in CRC (High Definition Single Cell Analysis of Blood and Tissue Biopsies	**32,389**	32,389
Biomarkers Consortium: Inflammatory Markers for Neurodegenerative and Mood Disorders	**632,750**	683,943
Biomarkers Consortium: Longitudinal CSF Proteomics	**-**	11,306
Biomarkers Consortium: MRD Project	**589,021**	819,021
Biomarkers Consortium: Novel Cardiac Biomarkers in the General US Population	**99,924**	116,732
Biomarkers Consortium: OA BMxQ	**504,169**	1,231,958
Biomarkers Consortium: Target BMx	**66,942**	82,526
Biomarkers Consortium: Vol-PACT	**75,747**	269,199
Biomarkers Consortium: PACT Implementation	**36,789,286**	42,959,963
Biomarkers for Early Detection of Preeclampsia	**356,039**	-
BC – Cachexia	**350,000**	350,000
Bradley Charitable Gift Annuity	**2,664**	10,240
Cancer Research Fund	**734,142**	1,443,911
Cancer Research Major Gift	**4,587,225**	4,587,225
Charles A. Sanders Legacy Fund	**1,126,187**	1,144,209
Chemotherapeutic Impact on the Immune MicroEnvironment	**85,614**	81,204
Comprehensive Cellular Vaccine Immune Monitoring Consortium (CVIMC)	**1,308,859**	6,875,918
Comprehensive Cellular Vaccine Immune Monitoring Consortium 2.0 (CVIMC 2.0)	**5,565,906**	-
Consensus Pathway for Gene Drive in Mosquitoes	**186,639**	186,570
ctDNA Reference Standards	**821,314**	877,809
CSC Symposium 2021	**29,576**	-
Developing Evidence-Based Music Therapies	**-**	61,850
Deeda Blair Research Initiative Fund for Disorders of the Brain	**482,293**	198,018
Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D	**-**	148,212
Fifth Annual Vivian Pinn Scientific Symposium	**5,419**	-
FNIH Travel support for NIH Scientists	**403,162**	404,330
Follicular Lymphoma Research Fund	**12,150**	7,650
GeneConvene Global Collaborative	**4,051,690**	4,095,702
Gilead HIV Cure Grants	**662,405**	1,414,971
Gramlich Melanoma Research Trust	**22,857**	200,751
Intelligent Sigh and Sound	**29,568**	-
iUFV (Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine)	**9,975**	441,240
Kidney Cancer Research	**200,552**	67,515
Lung Cancer Master Protocol (LungMAP)	**1,517,911**	2,314,428
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines	**83,863**	677,981
Minimal Residual Disease in Acuta Myeloid Leukemia (MRD-AML)	**1,485,000**	-
Mucosal Healing in Ulcerative Colitis	**1,593,871**	1,823,335
Neurofilament (Nf) as a Fluid Biomarker of Neurodegeneration	**1,944,388**	664,602
NCTN Data Archive De-Identification Project	**133,061**	133,931
Non-Invasive Biomarkers of Metabolic Liver Disease	**12,719,571**	5,959,610
NIP- Metastatic Prostate Cancer	**7,312**	48,646
OPIOIDS Stakeholder	**-**	100,000
Partnership to Accelerate Novel TB Regimens (PAN-TB)	**474,952**	527,210

Partnership for Gene Therapy Manufacturing Technologies	**19,102,059**	-
Pew Latin American Fellows Awards	**70,000**	-
Plasma Abeta Project	**1,842,522**	1,056,220
PREDICT-TB	**505,917**	876,312
Risk Assessment GeneConvene Interest	**1,992,344**	1,991,619
SHORTEN-TB	**25,436**	79,873
Solarz Memorial Fund	**16,232**	40,204
Structure-Based Vaccine D	**3,027**	11,167
SV2A PET Tracer as a Biomarker for Synaptic Density	**4,606,999**	1,150,447
The Lowy Cancer Research Support Fund	**3,812**	3,812
Tuberculosis Vaccine	**787,106**	220,022
Other Temporarily Restricted Programs	**579,267**	613,217
Total Temporarily Restricted Net Assets	**178,455,196**	131,899,601
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	**707,772**	707,771
CarMollNat Muscular Dystrophy Endowment	**61,249**	49,853
Futures Fund	**850,000**	847,632
Total Perpetual Endowments	**3,949,915**	3,936,150
	$ 182,405,111	$ 135,835,751

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, 2021:

	Without Donor Restrictions	With Donor Restrictions	Total
Board-designated endowment funds	**$ 18,686,885**	**$ -**	**$ 18,686,885**
Donor-restricted endowment funds:			
Original donor-restricted gift amount and amounts required to be maintained in perpetuity by donor	**-**	**3,949,915**	**3,949,917**
Accumulated investment gains	**-**	**1,874,334**	**1,874,332**
Total endowment funds	**$ 18,686,885**	**$ 5,824,249**	**$ 24,511,134**

The changes in endowment assets were as follows for 2021:

	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, beginning of year	**$ 15,549,000**	**$ 5,329,035**	**$ 20,878,035**
Investment return:			
Investment income	**-**	**207,994**	**207,994**
Net appreciation (realized and unrealized)	**-**	**336,670**	**336,670**
Total investment return	**-**	**544,664**	**544,664**
Contributions	**-**	**16,465**	**16,465**
Additional board designation	**3,137,885**	**-**	**3,137,885**
Appropriation of endowment assets for expenditure	**-**	**(65,915)**	**(65,915)**
Endowment net assets, end of year	**$ 18,686,885**	**$ 5,824,249**	**$ 24,511,134**

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

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 2021 and 2020, these in-kind contributions from NIH of $277,668 and $278,004, respectively, are reflected in the financial statements.

During 2021 and 2020, additional in-kind contributions of $3,659,164 and $322,482, respectively, 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 2021 and 2020, donated services of $16,900 and $49,500, 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 8% and 10% of annual salary from the Foundation in 2021 and 2020, respectively. Retirement plan expense for 2021 and 2020 was $702,994 and $844,686, respectively.

16. Concentration of Revenue

For 2021 and 2020, the Foundation received approximately 15% 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; corporate 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, 2021 and 2020:

	Assets at Fair Value as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
U.S. government bonds	**$ 64,776,949**	**$ -**	**$ -**	**$ 64,776,949**
Corporate bonds	**14,216,683**	**-**	**-**	**14,216,683**
Equity mutual funds	**13,063,833**	**-**	**-**	**13,063,833**
Bond mutual funds	**4,187,875**	**-**	**-**	**4,187,875**
Exchange traded funds	**5,284,295**	**-**	**-**	**5,284,295**
Total investments	**$101,529,635**	**$ -**	**$ -**	**$101,529,635**

	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

19. Conditional Grant Awards

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

	2021	2020
Accelerating Medicines Partnership: Type 2 Diabetes	$ **-**	$ 187,500
Accelerating Medicines Partnership: Parkinson's Disease	**173,527**	295,444
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**1,974,883**	3,002,968
iUFV (Combining Epitope-Based Vaccine Design with Informatic	**-**	383,942
Using Biomarkers to Predict TB Treatment Duration	**310,965**	973,926
GeneConvene	**2,327,641**	2,327,641
Biomarkers Consortium – Cardiac Troponin Project	**13,454**	13,454
Biomarkers – Target BMx	**50,000**	137,618
LungMaP (Lung Cancer Master Protocol)	**207,444**	376,590
Osteoarthritis (OA) Biomarkers Qualification (OA BMxQ)	**35,960**	56,228
Accelerating Medicines Partnership: Alzheimer's Disease	**1,474,000**	2,681,500
Efficay of Heterodimeric IL-15 Treatment Regimens	**-**	940,671
Understanding the Mechanisms of Intravenous BCG-induced Protection against TB in NHP	**975,813**	2,286,767
NIH Travel for Gates (FNIH Travel support for NIH Scientists)	**139,739**	139,739
Comprehensive Cellular Vaccine Immune Monitoring Consortium	**1,108,278**	534,936
CAR-T	**637,385**	1,313,141
WHO Pandemic Convention Consultations	**14,734**	-
mRNA encoded HIV Env-Gag virus-like-particle (VLP) vaccines	**170,000**	810,000
	$ 9,613,823	$ 16,462,065

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 $746,599 and $749,860, respectively, for 2021 and 2020.

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

2022	$ 722,172
2023	618,939
2024	919,084
2025	944,357
2026	970,986
Thereafter	5,728,692
	$ 9,904,230

21. Employee Retention Credit

In response to the economic impact of the COVID-19 pandemic, Congress introduced the Employee Retention Credit (ERC). The ERC is a refundable payroll tax credit available to taxpayers who experienced either a full or partial suspension of business operations due to government orders or had a significant drop in gross receipts during 2020 and 2021. The credit is only available for 50 percent of qualified wages with a maximum potential credit per qualified employee of $5,000 for 2020 and $7,000 per quarter for 2021.

The Foundation qualifies for the ERC based on a partial shutdown and has elected to account for the ERC as a government grant by analogy of ASC 958-605. Under ASC 958-605, the ERC may be recognized once the conditions attached to the grant have been substantially met. During 2020 and 2021, the Foundation incurred qualifying wages. During 2021 and 2020, the Foundation performed the ERC calculation and filed amended returns such that $913,617 and $350,943, respectively, of grant income has been recognized in the accompanying statements of activities. As of December 31, 2021, $347,757 of the 2020 ERC remains outstanding, recognized as a receivable on the accompanying statements of financial position.

22. 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.

The COVID-19 pandemic has impacted the operational activities of the Foundation’s business; however, the Foundation’s financial performance remained stable throughout 2020 and 2021. There is uncertainty in the nature and degree of its continued effects on the Foundation over time. 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 the Foundation’s customers, 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.

Foundation for the National Institutes of Health, Inc.

Compliance Section

Year Ended December 31, 2021

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, 2021, 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 6, 2022.

Report on 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 or significant deficiencies may exist that were not identified.

Report on 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 6, 2022

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 identified as subject to audit 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, 2021. 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.

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, 2021.

Basis for Opinion on the Major Federal Program

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). Our responsibilities under those standards and the Uniform Guidance are further described in the Auditor's Responsibilities for the Audit of Compliance section of our report.

We are required to be independent of Foundation for the National Institutes of Health, Inc. and to meet our other ethical responsibilities, in accordance with relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion on compliance for the major federal program. Our audit does not provide a legal determination of Foundation for the National Institutes of Health, Inc. 's compliance with the compliance requirements referred to above.

Responsibilities of Management for Compliance

Management is responsible for compliance with the requirements referred to above and for the design, implementation, and maintenance of effective internal control over compliance with the requirements of laws, statutes, regulations, rules, and provisions of contracts or grant agreements applicable to Foundation for the National Institutes of Health, Inc.'s federal program.

DHG

Auditors' Responsibilities for Audit of Compliance

Our objectives are to obtain reasonable assurance about whether material noncompliance with the compliance requirements referred to above occurred, whether due to fraud or error, and express an opinion on Foundation for the National Institutes of Health, Inc. 's compliance based on our audit. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance will always detect material noncompliance when it exists. The risk of not detecting material noncompliance resulting from fraud is higher than for that resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Noncompliance with the compliance requirements referred to above is considered material if there is a substantial likelihood that, individually or in the aggregate, it would influence the judgment made by a reasonable user of the report on compliance about Foundation for the National Institutes of Health, Inc.'s compliance with the requirements of the major federal program as a whole.

In performing an audit in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material noncompliance, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding Foundation for the National Institutes of Health, Inc.'s compliance with the compliance requirements referred to above and performing such other procedures as we considered necessary in the circumstances.
- Obtain an understanding of Foundation for the National Institutes of Health, Inc.'s internal control over compliance relevant to the audit in order to design audit procedures that are appropriate in the circumstances 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 Foundation for the National Institutes of Health, Inc.'s internal control over compliance. Accordingly, no such opinion is expressed.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and any significant deficiencies and material weaknesses in internal control over compliance that we identified during the audit.

Report on 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 Auditors' Responsibilities for the Audit of Compliance section above and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies in internal control over compliance. Given these limitations, during our audit we did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses, as defined above. However, material weaknesses or significant deficiencies in internal control over compliance may exist that were not identified.

Our audit was not designed for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, no such opinion is expressed.

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 6, 2022

Foundation for the National Institutes of Health, Inc
Schedule of Expenditures of Federal Awards
For the Year Ended December 31, 2021

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	$ 4,395,399	$ -
Total Expenditures of Federal Awards				$ 4,395,399	$ -

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, 2021. 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

None

Annual Report

Access at
fnih.org/2021annualreport

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National Institutes of Health

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