



## Congress of the United States

## House of Representatives

Washington. DC 20515

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May 10, 2024

The Honorable Tom Cole Chairman House Appropriations Committee Washington, DC 20515 The Honorable Rosa DeLauro Ranking Member House Appropriations Committee Washington, DC 20515

Dear Chairman Cole and Ranking Member DeLauro:

I am requesting funding for Advancing Medical Research with a Genetically Varied Biobank in fiscal year 2025. The entity to receive funding for this project is NYSCF, located at 619 West 54th Street, 3rd Floor, New York, NY 10019. The funding would be used for the advancement of NYSCF's work.

Prior to 2005, the stem cell field was virtually nonexistent. Stem cells had recently been discovered as a powerful tool for understanding disease and developing new treatments, but the field lacked the funding, talent, and laboratories needed to capitalize on this technology. The New York Stem Cell Foundation (NYSCF) was launched with the mission of using stem cell research to accelerate treatments and cures for the major diseases of our time. This catalyzed the growth of the field, which now includes thousands of scientists worldwide conducting groundbreaking research across many diseases.

Since NYSCF's founding, we have boldly pursued the high-risk, high-reward research not funded by traditional mechanisms. NYSCF opened its first laboratory in 2006 and in 2015 built a new 40,000 square foot Research Institute to conduct cutting-edge research. Our work has resulted in numerous publications, collaborations with researchers from leading institutes across the globe, and the advancement of new therapies closer to the clinic. This includes a cell therapy for treating age-related macular degeneration, a technique called mitochondrial replacement therapy that prevents the inheritance of devastating mitochondrial diseases in children, and novel approaches to the treatment of various cancers.

Disease risk and drug efficacy varies across individuals, with significant disparities across different groups. Much of what we know about diseases and drugs does not apply to populations who have historically been underrepresented in clinical research. Our project proposes the creation of a biobank of 100 genetically varied induced pluripotent stem cells (iPSCs) to serve as a reference standard, ensuring that therapeutic developments are both effective and safe across all populations.

iPSCs are a type of stem cell created through a process in which scientists take a small sample of skin or blood and revert them to a stem cell. iPSCs can be made from anyone's blood or skin, can grow indefinitely in the laboratory, and can be turned into any type of cell in the body, giving researchers a limitless supply to advance the understanding and treatment of diseases.

For this project, which would be funded through the National Institute of Standard and Technology (NIST) Scientific and Technical Research and Services (STRS) program, we will invest in new advanced equipment to empower our high-throughput automated systems, optimizing the generation of iPSCs with precision and consistency. Our team will also utilize NYSCF's existing automation platform to scale up the production of stem cell lines, maintaining stringent quality control measures to ensure each cell line meets gold-standard benchmarks. NYSCF's automation systems will ensure that the biobank is a reliable, reproducible, and representative resource for the development of universally effective and safe therapeutics, regardless of ancestry.

Funding for this project will be used to purchase two pieces of critical and sophisticated equipment that uses a technique called flow cytometry to provide detailed analyses of cells. This is critical for developing new quality control standards and ensuring the stem cells we create can be used as reference materials for our scientists and others using cells in the biobank.

Funding will also be used for salaries of NYSCF scientists and employees who will collect blood samples from individuals and turn those patient samples into stem cells. The supplies needed for creating these 100 stem cell lines will also be supported by this request.

This will result in the largest known biobank of diverse stem cell lines that will enhance the reproducibility of clinical research across all ethnic groups, contributing to reliability and reproducibility of biomedical research.

Funding this project benefits the constituents of New York's 12<sup>th</sup> Congressional District as it propels medical advancements that promise better health outcomes and cost-efficient therapies, effectively reducing the long-term healthcare burden on public funds. This biobank would place the district at the forefront of personalized medicine, potentially attracting investments and fostering high-tech job creation. Creating a set of reference standard stem cell lines from an ethnically diverse population will ensure that the diverse population of New York and this district is represented in, and benefits from, the next generation of medical breakthroughs. This reinforces New York's commitment to health equity and positions the community to lead by example in the implementation of standardized, inclusive therapeutic development.

This project only relates to stems cells derived from adult cells (skin and blood). This type of cell has been supported and highlighted in the past by President George W. Bush and others who were opposed to embryonic stem cells. There are no stem cells in the project being created from embryos or aborted fetal tissue.

This project does not include any renovation costs of any kind, just salaries and equipment. All salaries included in the project are for one year. I have included the budget breakdown below:

- Personnel Salaries: \$565,000
  - Project Director (CDS would cover 33% of salary) \$75K Oversees project to ensure program goal is met, supervision of staff, liaison for organizational leadership, dissemination of results

- Clinical Research Director (50%) \$95K Research coordinator overseeing collection of blood samples
- Scientist (50%) \$85K PhD scientist who coordinates all cell line generation and offers troubleshooting and technical assistance as needed
- Technician (100%) \$105K Day-to-day experimental work to convert blood samples into stem cell lines
- Technician (100%) \$105K Day-to-day experimental work to convert blood samples into stem cell lines
- QC Technician (50%) \$65K Performs all quality control assays to ensure that the cells created meet rigorous standards and receive certificates of analysis prior to storage in biobank and further use in research
- Nurse (50%) \$35K Collection of blood samples from biobank participants
- Experimental supplies: \$415,000 All laboratory plasticware, reagents, media for the generation and maintenance of stem cell lines
- Equipment: \$956,000 cell sorting equipment for automating the quality control of stem cell creation, creating standardized tests, reference libraries, and contributing to the reproducibility of data
- Total: \$1,936,000

This project is scalable. The minimum dollar amount needed to sustain this project is \$956,000.

The project has a Federal nexus because the funding provided is for purposes authorized by section 20102 of title 51, United States Code.

I certify that I have no financial interest in this project, nor does anyone in my immediate family.

Sincerely,

Jerrold Nadler

Member of Congress

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