



Department of Health and Human Services
National Institutes of Health



Common Fund Strategic Planning Report

2015



National Institutes of Health
Office of Strategic Coordination - The Common Fund



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DIRECTOR'S MESSAGE

The Office of Strategic Coordination (OSC) in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) at the National Institutes of Health (NIH) manages the Common Fund, and is pleased to present the 2015 Strategic Planning Report. The Common Fund supports short-term (5-10 year) strategic investments that are intended to transform the biomedical research landscape through the development of catalytic tools, resources, and datasets; discovery of new biological paradigms; or piloting new approaches to support innovation in the biomedical research enterprise. Each Common Fund program is the product of a rigorous strategic planning process, with defined goals and set milestones that are crafted to achieve breakthroughs. This report articulates the mission of the Common Fund and how strategic planning structures the goals and milestones of its programs. It describes new approaches for strategic planning in the future and outcomes of past planning activities.



*James M. Anderson, M.D., Ph.D.
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Initiatives*

In 2014, the Common Fund celebrated 10 years of support for the biomedical community. Over the past decade, the Common Fund has supported more than 30 programs designed to change the way science is conducted, and the benefits of these programs are now being realized. As part of our 10 year anniversary, we engaged the NIH Council of Councils in evaluating the processes used to plan for and manage the Common Fund. As described in this report, the recommendations related to strategic planning are now being implemented as we plan for new programs in fiscal years 2018 and beyond. These improved processes include enhanced opportunities for NIH Institute and Center Directors to provide feedback as new program plans are developed and ensure that NIH stakeholders have the opportunity to provide input as concepts for new programs are developed.

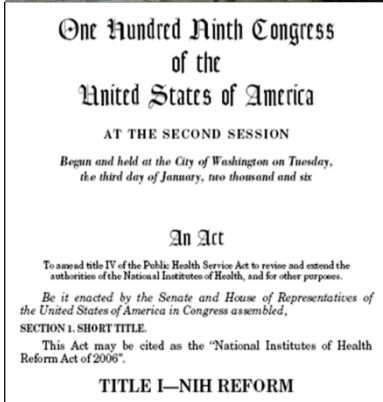


*Elizabeth L. Wilder, Ph.D.
Director, Office of Strategic
Coordination*

The success of Common Fund programs results from the dedication of countless NIH staff members and the creative, enthusiastic research community that has embraced the Common Fund mission. Identifying strategic areas to invest in requires input from diverse communities that collectively consider the cutting edges of biomedical and behavioral research to determine where Common Fund support can have the biggest impact. This planning process is unusual in its demand that programs have impact within ten years and in its expectation that goals and milestones be defined. The programs that result are transforming a multitude of fields across biomedical research with the ultimate goal of improving human health.

James M. Anderson Elizabeth L. Wilder

ABOUT THE COMMON FUND



The origins of the Common Fund lie in the NIH Roadmap for Medical Research, which was launched in 2004. The NIH Reform Act of 2006 created the Common Fund as a source of support for these transformative, trans-NIH programs within the Office of the Director. This established a novel approach to support cross-cutting, trans-NIH programs in areas of emerging scientific opportunities, rising public health challenges, and knowledge gaps that deserved special emphasis or would otherwise benefit from strategic planning and coordination. The Reform Act also mandated an emphasis on goals and milestones in Common Fund programs and directed the NIH to encourage participation by early career investigators.

The Office of Strategic Coordination (OSC) within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) is responsible for managing the Common Fund. OSC coordinates trans-NIH teams who collectively plan, implement, and oversee each program to ensure broad impact. Individual awards supported through the Common Fund are administered by the NIH Institutes and Centers (ICs).

OUR MISSION:

Common Fund programs represent strategic investments in which 5 to 10-year initiatives can have a transformative impact. Common Fund programs change the way science is conducted – through the establishment of new scientific fields or paradigms, the development of new and innovative technologies or methods that change the way scientists approach their work, or the generation of comprehensive data sets or other resources that catalyze investigator-initiated research and enable discovery. Common Fund programs are designed to be relevant to multiple diseases and conditions, and to enable discovery broadly across the biomedical/behavioral (referred to throughout this document as “biomedical”) research community.

OUR VISION:

The intent of the Common Fund is to provide a strategic approach to identify key roadblocks in biomedical research that impede basic scientific discovery and its translation to improved human health, to determine whether opportunities exist to overcome these challenges, and then to implement a coordinated set of initiatives that collectively deliver a solution. The Common Fund is also intended to provide a mechanism for investment in emerging areas of science that may reveal fundamentally new biomedical paradigms. The work supported by the Common Fund is inherently risky, but this risk is embraced due to the potential for transformative impact in advancing science and, ultimately, improving human health.

ABOUT THE STRATEGIC PLANNING REPORT

The Public Health Service Act requires the Director of the NIH to submit a report to Congress containing a strategic plan for funding research that "...represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning" (42 U.S.C. §§ 282(b)(7)(A), 283(a)(3)).

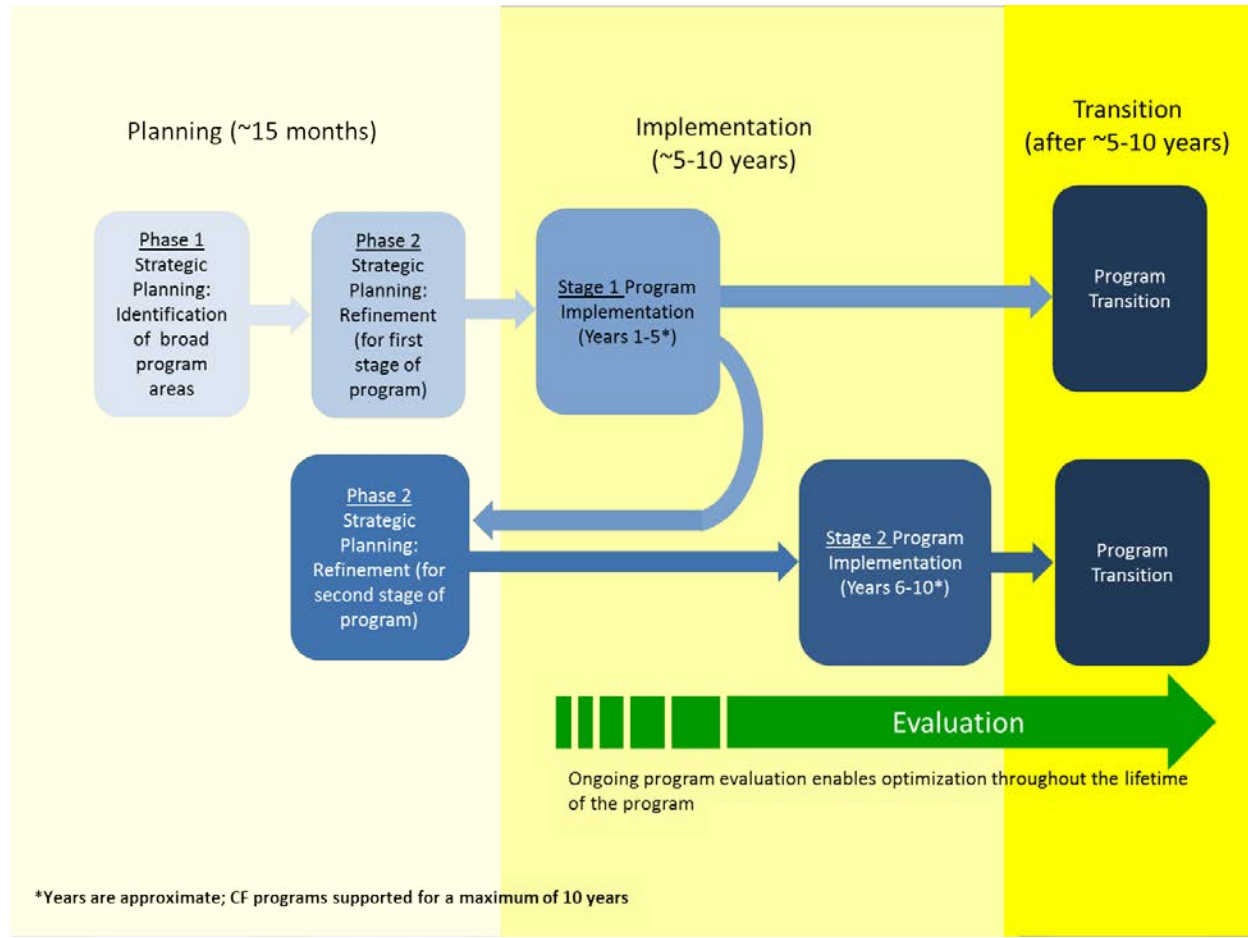
THE COMMON FUND PROGRAM LIFECYCLE

Common Fund programs establish goals and milestones that are expected to be achieved in a 5 to 10-year period. These programs are identified through a strategic planning process that includes input from many stakeholders who first identify broad scientific areas that are priorities for the NIH as a whole and then subsequently establish a focused strategy for investments that will catalyze progress within that area. This process ensures that the programs provide maximum utility to the broad biomedical community and that they address major roadblocks to research progress. Since Common Fund programs are intended to benefit biomedical research very broadly, each program is administered and guided by staff from multiple NIH ICs. At the completion of each program, the tools, technologies, and data produced by the program are taken up and used by the community at large, and/or the infrastructure that the Common Fund has built transitions to other sources of support.

Common Fund strategic planning is a two phase process. Phase 1 of strategic planning identifies broad areas that are high priorities for the NIH and for which transformational progress can be envisioned. Phase 2 of strategic planning involves an analysis of the scientific landscape within a given field to identify the specific challenges and opportunities for progress. Programmatic goals are established, with a series of funding initiatives collectively designed to achieve those goals.

Following strategic planning and selection of new program areas, goals and milestones identified during the planning process are implemented through a variety of funding mechanisms - typically as five-year awards known as "cooperative agreements." Awards are implemented as partnerships between scientific investigators and the NIH to achieve defined goals. These partnerships, or consortia, represent coordinated efforts that result in integrated data sets, complementary tool and technology development, or fundamental paradigms that result from integrated data analysis. Common Fund programs are actively managed to ensure that the output of each program is maximally useful to the broader scientific community. Assessment of the utility of the program to the community is emphasized and is achieved through a variety of evaluative processes.

Nearing the end of the first five years, Phase 2 of strategic planning is revisited to determine if new challenges and opportunities have emerged within this scientific area and if continued investment by the Common Fund will maximize the program's impact during a second period of support. The final phase of Common Fund support involves the transition of mature programs to other sources of support or use within the scientific community.



Schematic representing the Common Fund's strategic planning process

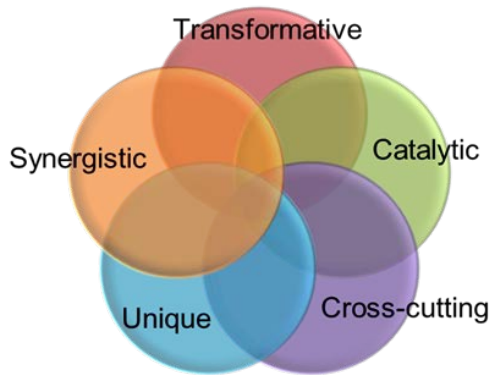
Although represented as sequential activities, there is an iterative nature to the management of each program. Plans for implementation and transition are considered at the early phases, but may be adapted in response to the science. Similarly, scientific progress may demand changes in the strategic plan, as new opportunities or challenges are identified. Nevertheless, early consideration of implementation and transition ensure that program goals and milestones are established to meet the needs identified during strategic planning and to provide a sustainable model for continued use by the scientific community once Common Fund support for a program has ended.

THE COMMON FUND STRATEGIC PLANNING PROCESS

GOALS OF STRATEGIC PLANNING

Strategic planning for the Common Fund is flexible from year to year in order to adapt to emerging opportunities, the changing needs of the scientific community, and the availability of funds. Specific processes can vary slightly from year to year; however, core principles and activities underlie all planning activities. These include:

- Using defined criteria to select Common Fund programs. Since many areas of science are relevant to multiple NIH ICs, the NIH Director and IC Directors established defined criteria for the NIH Roadmap which remain essentially unchanged for Common Fund programs. These criteria, described on the next page, ensure that Common Fund programs fill niches in high priority areas that would otherwise unlikely be supported due to the expense and/or the high degree of trans-NIH coordination required.
- Gathering input from diverse perspectives. Common Fund planning engages experts from a wide range of scientific disciplines and career stages. All of the NIH ICs, the NIH Council of Councils (hereafter referred to as the Council), and external scientists who represent trans-NIH research interests provide input. The NIH Council of Public Representatives provides input via a representative on the Council, and input from the broader public may be gathered through Requests for Information or online discussions.
- Systematically collecting input. Input is gathered systematically and transparently. Many ideas for possible Common Fund programs can be envisioned; however, only a small number can actually be supported. Therefore, the process for soliciting ideas must involve the review and prioritization of many ideas together. This way, competition among many ideas will result in the most compelling programs.
- Analyzing the relevant scientific landscape. Analysis of ongoing research related to the proposed program, supported by the NIH or other sources, is a critical component of the strategic planning process. Portfolio review is an iterative process that helps in the selection of broad program areas, as well as the development of specific initiatives within these broad areas. This ensures that the Common Fund initiatives synergize with and do not duplicate ongoing efforts and that relevant groups work together for accelerated progress.
- Engaging the NIH leadership. The leadership across NIH must be engaged early in the selection of new program areas to ensure that program development is focused on areas for which there is significant enthusiasm and potential for broad impact.

CRITERIA FOR COMMON FUND PROGRAMS

Common Fund Programs are intended to be:

Transformative:

Must have high potential to dramatically affect biomedical research over the next decade

Catalytic:

Must achieve a defined set of high impact goals within a defined period of time (5-10 years)

Synergistic:

Outcomes must synergistically promote and advance individual missions of NIH ICs to benefit health

Cross-cutting:

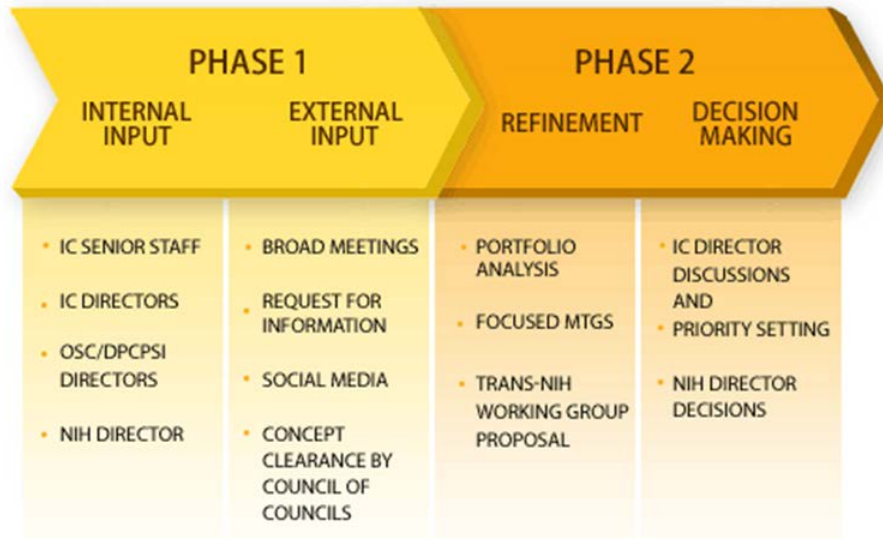
Program areas must cut across missions of multiple NIH ICs, be relevant to multiple diseases or conditions, and be sufficiently complex to require a coordinated, trans-NIH approach

Unique:

Must be something no other entity is likely or able to do

STRATEGIC PLANNING PROCESS (PHASE 1 and 2)

Strategic planning involves the identification of trans-NIH challenges and opportunities that address the Common Fund criteria. Broad topics identified in **Phase 1** are refined into a series of well-defined programs and initiatives in **Phase 2**.



Phase 1 identifies broad scientific needs and opportunities through meetings with external scientific experts, solicitation of ideas from NIH ICs, discussions with NIH Leadership and Advisory Committees, and/or engagement with the broader scientific community. The Council considers Phase 1 concepts and provides advice to the DPCPSI and NIH Directors with respect to those concepts that are likely to have the highest impact.

Strategic planning efforts focus on identifying the **greatest challenges** to research discovery and translation and the most promising **emerging opportunities** to catalyze research across a variety of scientific disciplines and disease conditions.

To effectively evaluate the responsiveness of the proposed idea to Common Fund criteria, as well as the potential impact of the program, the following questions are posed:

- What is the major obstacle/challenge/opportunity that the Common Fund should address?
- What are the goals of the program?
- Why is a trans-NIH strategy needed to achieve these goals?
- What initiatives might form the strategic plan for this topic?
- If a Common Fund program on this topic achieved its objectives, what would be the impact?

Concepts cleared by the Council are prioritized by IC, DPCPSI, and NIH Directors to identify which should move to the Phase 2 planning stage.

Phase 2 refines the broad concepts identified in Phase 1 into specific, well-defined initiatives. The refinement process includes external and internal meetings and workshops, analysis of the NIH and external scientific research portfolios, trans-NIH Working Group proposals, and priority setting by IC, DPCPSI, and NIH Directors.

Phase 2 planning produces a unique strategic plan that will be implemented for each program, which includes well-defined goals and milestones. Each Common Fund program includes a plan for active program management for the duration of Common Fund support to ensure goals and milestones are being met and to allow flexibility to adjust to the changing needs of the research community and the current state of the science. The implementation plan for each program is reviewed and adjusted annually through program reviews conducted in partnership by the administering ICs and DPCPSI/OSC.

Portfolio analysis occurs during Phase 2 of the strategic planning process. It is a vital part of strategic planning that provides critical information concerning ongoing efforts in areas being considered as potential Common Fund programs. Portfolio analysis helps to identify specific areas where strategic investment by the Common Fund could support unique and potentially transformative research.

Example: Portfolio Analysis for Enabling Exploration of the Eukaryotic Epitranscriptome (E⁴)

This proposed program builds on recent discoveries that RNA molecules are modified in diverse ways in mammalian cells, modifications that have been studied are functionally significant for diverse biological processes, and experimental tools and methods have been critical for the analysis of these molecules. Since many modifications have not been functionally assessed, fundamental new biological paradigms may emerge by studying these processes. However, existing tools only allow analysis of one or a few modifications. The purpose of this portfolio analysis was to assess current funding in this area so that gaps may be identified. The following questions were addressed:

- To what extent is epitranscriptomic research being supported by the NIH and other entities?
- What RNA modifications are being studied?
- Does current funding address the paucity of research tools available?

Key findings from this portfolio analysis found that there were no major epitranscriptomics efforts currently being supported by the NIH or other entities. Additionally, the majority of NIH funding supports grants investigating only two of the many RNA modifications. Only 44 funded NIH extramural grants investigated modifications other than the most common modification and NIH supports limited tool and technology development in this area. 85% of these grants focus on bacteria, fungi, invertebrates, or other cell culture systems, so relatively few studies are examining these modifications in mammals.

The results of the portfolio analysis highlighted areas in the field of epitranscriptomics that could benefit from Common Fund support. The E⁴ Working Group recommended that strategic investment by the Common Fund should focus on:

- diverse RNA modifications, other than the two currently studied
- development of new tools and technologies
- *in vivo* mammalian studies

Phase 2 strategic planning also occurs before decisions are made to provide a second stage of support for existing programs. OSC assesses the progress of Common Fund programs at the end of the first stage of funding to determine whether a second stage of funding (up to a limit of 10 years total) is necessary to reap maximum benefit from the program. Program assessment is a critical component of strategic planning for a second stage. Portfolio analysis determines whether the field has expanded significantly since the program began; dramatic expansion can be a sign of success of the program, but it also may reduce the need for continued dedicated investment by the Common Fund. Expert review is also critical for decisions about a second stage of support for a program. Reviews engage end-users of data or tools to assess utility of the deliverables to date. They also engage experts who can help determine whether methods and tools are truly state of the art. The experts provide valuable insight in helping to determine whether continuation of the existing program is a top priority and whether there is a compelling scientific need for the program to be continued. Regular assessments of the program by external scientists as part of routine program oversight also help guide the development and decision-making for each program and help determine how the programs should be adapted in future years to meet the changing needs of the scientific community.

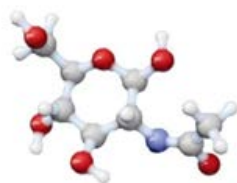
STRATEGIC PLANNING ACTIVITIES SINCE 2013

The Common Fund Strategic Planning Report for 2013 (http://commonfund.nih.gov/sites/default/files/Rnd2a_2013_Strategic_Planning_Rept_NIH_0.pdf) described strategic planning activities and the current status of programs emerging from those activities. New rounds of strategic planning started in 2013 and 2014, leading to new programs being implemented in fiscal year 2015 and planned for fiscal year 2016 and beyond, pending availability of funds.

Strategic Planning in 2013:

The 2013 federal budget sequester sharply curtailed conference spending and caused uncertainty about budget availability for new and continuing Common Fund programs in the upcoming years. Therefore, plans for Common Fund strategic planning conferences were postponed with the intent of holding these conferences every 2-3 years. Instead, IC Directors were asked to represent their communities and put forward ideas for new programs since they have extensive and continuous interactions with external scientists. The resulting ideas were discussed by the Council, and three concepts were subsequently selected to move into Phase 2 planning. A fourth concept addressing modulation of the peripheral nervous system was established later that year as a result of a conference co-led by NIH, DARPA, and GlaxoSmithKline and which involved several potential industry partners. The concepts below were approved for implementation beginning in fiscal year 2015 and are described in Table 1. The remaining concept, a proposed program investigating the mechanisms of benefits of physical activity, required additional planning so was deferred to another fiscal year.

- 4D Nucleome (4DN)
- Glycoscience
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)



GLYCOSCIENCE



Stimulating Peripheral Activity to Relieve Conditions (SPARC)

Table 1: Strategic Planning Goals of New Programs to be Launched in Fiscal Year 2015

Common Fund Programs	Strategic Goals
<p><u>4D Nucleome</u></p> <p><i>Challenge/Opportunity</i> - Genetic material, located within the nucleus of the cell, is not randomly organized. Although the organization of the nucleus is known to influence cellular function, how this occurs is not understood. The 4D Nucleome program aims to overcome technological hurdles and knowledge gaps to enhance our understanding of how nuclear organization in space and time influences human health and disease.</p>	<ul style="list-style-type: none"> ▪ Enable research that explores the relationship between nuclear organization and regulation of gene expression in development and disease ▪ Develop and validate novel approaches and technologies leading to a deeper understanding of three-dimensional nuclear organization in space and time (the fourth dimension), and its function in regulating gene expression and cellular function/or other nuclear processes ▪ Decrease current limitations in exploring 4D nuclear conformation through the development of novel and improved tools and technologies that are easily adopted by the scientific community ▪ Develop a community website to facilitate sharing of data, analytic tools, reagents, standards, and protocols between 4D Nucleome investigators and the larger scientific community
<p><u>Glycoscience</u></p> <p><i>Challenge/Opportunity</i> – All cells carry an array of sugars, or glycans, that play important roles in many biological functions. However, the complexity of carbohydrate chemistry makes the analysis of glycans inaccessible to most biomedical researchers. The Glycoscience program aims to overcome this obstacle by developing resources, tools, and technologies to make the study of glycans accessible to the broad biomedical research community.</p>	<ul style="list-style-type: none"> ▪ Develop new approaches for rapid and inexpensive synthesis of large quantities of glycans in order to understand their roles in biological process and diseases ▪ Develop new, easily accessible tools – methods, reagents and technologies – to facilitate identification, tracking, manipulation, and analysis of glycans and their functions ▪ Develop new informatics tools to facilitate the analysis of glycan data and integrate it with gene and protein data
<p><u>Stimulating Peripheral Activity to Relieve Conditions (SPARC)</u></p> <p><i>Challenge/Opportunity</i> – Modulation of nerve signals (neuromodulation) of end-organ function holds promise in treating many diseases/conditions, but the mechanisms of action for therapies remains poorly understood. SPARC aims to capitalize on recent technology developments to establish the scientific foundation and catalytic resources for development of new or more efficacious therapies based on neuromodulation of organ function.</p>	<ul style="list-style-type: none"> ▪ Deliver detailed, integrated functional and anatomical neural circuit maps in five organ systems; use the maps to develop and pilot novel electrode designs, stimulation protocols, and minimally invasive surgical procedures ▪ Develop next-generation tools to stimulate, trace, and manipulate visceral nerves ▪ Partner with industry and the FDA to explore the use of existing, approved devices to address new opportunities in small markets ▪ Assemble data from all SPARC biology/technology projects into a coordinated data resource; develop user-friendly computational tools and incorporate new computer modeling methods

In addition to these new programs, three existing programs underwent planning for a second period of support and were approved for a second stage to begin in fiscal year 2015. These programs are:

Science of Behavior Change (SOBC): An Expert Review Panel (ERP) convened in 2014 to evaluate the progress of the SOBC program, and individuals within the ERP provided input for future directions and activities. This review established that the first stage of support was successful in encouraging investigators to adopt mechanism-based approaches to explore behavioral interventions, but several participants indicated that a new, coordinated effort was required to establish these approaches broadly within the field. This review also highlighted the need to compile research studies so that the field as a whole could assess new research methods and compare approaches. To address these concerns in the second stage, the SOBC program will support a consortium of investigators who will identify the mechanisms through which behavioral interventions work, focusing on interventions designed to modify behaviors of relevance to every NIH IC; specifically, adherence to medical treatment. The program will also establish a central repository for investigators to submit information. Investigators will disseminate new mechanism-based experimental methods through various approaches designed to reach the next generation of researchers.

NIH Center for Regenerative Medicine (CRM): The goal of the NIH CRM is to resolve translational challenges associated with the use of induced pluripotent stem cells (iPSCs). This goal was addressed in the first stage of the program through a series of pilot projects that included generation of cell lines and protocols. Notably, this stage resulted in a contract for the production of an iPSC line through clinical grade manufacturing processes to enable the use of these cells in humans. This cell line will be the first publicly available one of its kind and will be available in summer 2015. In the second stage of the program, one of the pilots is moving forward toward a clinical trial to treat advanced age-related macular degeneration, a leading cause of blindness. This project will navigate translational and regulatory hurdles that will pave the way for future projects. In addition, NIH CRM will establish a new facility within the National Center for the Advancement of Translational Sciences (NCATS) with three goals: 1) establish detailed quality control (QC) standards to define differentiated cell types and pluripotency; 2) develop methods to assess heterogeneity in iPSC-derived cells; and 3) develop standardized methods to produce mature cells meeting the QC standards above. To inform the second stage, the NIH held a workshop that included experts from academia, industry, scientific societies, and other federal government agencies that provided input regarding high priority gaps and challenges in the area of stem cell research.

Medical Education Partnership Initiative (MEPI; part of the Global Health program): The Common Fund's Global Health program has the overarching goal of expanding research capacity in under-developed international settings to benefit human health. Initiatives within this program leverage substantial funding by partner organizations to achieve global health goals. The Common Fund component of the MEPI initiative builds from a significant investment by the President's Emergency Program for AIDS Relief (PEPFAR) to build medical clinical and research capacity in Africa. While the PEPFAR investment emphasizes training physicians to treat AIDS patients, the Common Fund investment broadened the training and research opportunities to other areas. Building from this initial stage of the program, the second stage of MEPI will increase the capacity of MEPI institution faculty to pursue careers that include research. This program intends to provide both research training and mentored research opportunities for entry-level to mid-level faculty in MEPI-supported African institutions.

Strategic Planning in 2014:

Strategic planning processes underwent a detailed review by the Council in 2014 (as described on page 14). Four existing programs were projected to require a second stage of support beginning in fiscal year 2016 or fiscal year 2017. For these reasons, Phase 1 strategic planning to identify new programs sought input from IC Directors, but did not involve external conferences. OSC is planning for a broad-based Phase 1 process to be conducted in 2015 using recommendations from the Council review.

One new program concept, “Enabling Exploration of the Eukaryotic Epitranscriptome,” was selected for further development via Phase 2 planning as a result of input from IC Directors. In addition, another concept from the 2013 process, “Mechanisms of Physical Activity Benefit,” was further developed. These program concepts currently remain in the planning stages and are broadly described below.

- *Enabling Exploration of the Eukaryotic Epitranscriptome (E4)*: This program aims to develop tools and resources to enable the systematic study of RNA modifications, collectively known as the epitranscriptome, and their role in human health and disease. Exploration of these modifications is at a very early stage, but they are thought to play functionally significant roles. This program has the potential to provide fundamental new paradigms about regulation of RNA and the myriad cellular processes that RNA controls.
- *Mechanisms of Physical Activity Benefit*: This program would identify molecules that mediate benefits from physical activity to multiple organ systems. It would provide data from humans, and potentially animal models, undergoing a variety of physical activity regimens so that researchers interested in many different health conditions can mine these data to explore mechanisms through which physical activity is beneficial. This is expected to enable tailored “prescriptions” of physical activity based on individual health status and potentially to therapies that improve health through mimicry of physical activity.

Of the four existing programs that were under consideration for a second phase of support, one underwent a review that resulted in a decision not to pursue a second stage. The Protein Capture Reagents program was established as a pilot program to determine whether existing or newly developed technologies could be scaled up to produce research tools, or capture reagents, that would allow every human protein to be isolated for analysis. As the pilot phase was coming to an end, both of these objectives were reviewed by expert panels, with the conclusion that neither existing nor new technologies could meet the high risk, high throughput objective that was required for the program as a whole. The review also revealed that the protein capture reagents that had been developed to date through the program were not being utilized by the community. A number of factors, including lack of independent validation of the reagents, lack of scientific community awareness, and provision of some of the reagents in a sub-optimum form, were identified as contributing to low user satisfaction. This exemplifies the utility of expert review, as well as user-focused metrics, in determining how to manage Common Fund programs. As the pilot phase concludes, a contract for independent validation and production of the reagents will be supported in order to maximize the impact of the investment.

The three remaining programs that are under consideration for a possible second stage of support are still undergoing further planning. These programs are described below.

Illuminating the Druggable Genome (IDG): IDG began as a two year exploratory program to compile data about the four protein classes that are most frequently targeted by drugs. Many members of these protein classes are relatively uncharacterized, but may play important roles in disease processes, and therefore may represent new drug targets. As the exploratory phase of this program concludes, a focus on the least characterized proteins is emerging for a possible second stage.

Knockout Mouse Phenotyping Program (KOMP2): KOMP2 has sought to provide functional information on every gene in the mouse genome. It takes advantage of a pre-Common Fund effort to systematically “knock out” every gene in the genome in stem cells. The stem cells are developed into live mice and standardized analyses are conducted to determine the results of the loss of each gene. The first stage of KOMP2 is conducted via extensive international collaborations and is on track to cover approximately one third of the genome. A second stage of this program would continue work from the first stage so that all of the genes are analyzed.

Human Heredity and Health in Africa (H3Africa, part of the Global Health program): The H3Africa program aimed to increase capacity for genomic research in Africa through support of research, infrastructure, and training. This is enabling partnerships between African and U.S. investigators on a number of critical biomedical topics, including the recent Ebola outbreak and genetic contributions to many common diseases. A second stage of this program would involve continued development of new sample repositories, bioinformatic infrastructure, training programs, and pilot research efforts. This program is expected to enable African scientists to be competitive in international research efforts in the future, so that the Common Fund investments will have a sustained impact.

In addition, the Gabriella Miller Kids First Research Act will be implemented in fiscal year 2015.

In 2014, the **Gabriella Miller Kids First Research Act** authorized \$12.6 million each year for 10 years to the Common Fund in the area of pediatric research. This funding was appropriated to the Common Fund in fiscal year 2015, and planning efforts are underway to identify areas for which strategic investment by the Common Fund can have the most significant impact. Planning activities are currently focused on gathering input from NIH staff and external experts in pediatric research in order to identify the greatest needs and opportunities in this field.

EVALUATION OF COMMON FUND PLANNING AND MANAGEMENT PROCESSES

2014 was the tenth year of the Common Fund. These programs began as an experiment in trans-NIH planning and program management, so the Council was asked to undertake a systematic review of the processes through which the Common Fund is managed. Their recommendations can be summarized as follows:

- Engage a broad group of stakeholders (e.g., thought leaders from the external scientific community, NIH IC Directors and staff, NIH advisory committees, and public representatives) to gather and formulate ideas, using methods that ensure participants understand Common Fund criteria
- Clarify the criteria for new Common Fund programs, including those which address urgent scientific needs and those that involve allocation of funds to NIH intramural investigators
- Provide opportunities for increased or richer participation by the IC Directors and the Council as concepts are developed and selected
- Enhance the partnership between OSC and the ICs through improved working relationships, communication, and transparency as concepts are developed and selected

The OSC convened a multi-IC group to consider these recommendations and develop plans to implement them. These implementation plans were presented to the IC Directors in November 2014, and their suggestions were incorporated. The plans were presented to the Council at its January 2015 meeting and will be implemented in 2015 for programs that will begin with fiscal year 2018 funds.

Engage a broad group of stakeholders to gather and shape ideas.

The key lesson learned from strategic planning to date is that the articulation of concepts that meet expectations for the Common Fund – “Common Fund’able concepts” – requires iterative discussion. The breadth of the science that could potentially be supported by the Common Fund makes the identification and specification of new programs challenging; specifically, programs must not only address broadly relevant challenges, they must articulate specific goals and deliverables to have a transformative, catalytic impact on the field within a 5-10 year timeframe.

- In Phase 1 planning, OSC will use a variety of approaches to gather input from NIH stakeholders, tailoring the planning activities each year in anticipation of funding availability. Meetings of external scientists and broad solicitation of input using social media or RFIs will occur approximately biannually. In addition to local meetings, OSC will begin to take greater advantage of national conferences to meet with stakeholders and brainstorm about potential new program areas and enhancement of existing Common Fund programs. In the years when this type of broad outreach is not undertaken, concepts for new programs will be solicited from IC Directors if funds are expected to be available. OSC Program Leaders and OSC/DPCPSI Leadership will be active participants in meetings with external scientists and in discussions with NIH staff to facilitate the formulation of concepts that meet the expectations for the Common Fund.
- As described below, the IC Directors will be engaged early in the process to help select and shape concepts to be discussed with the Council. This will help to ensure that concepts that are considered by the Council are priorities for the ICs and have sufficient detail to allow an informed discussion by the Council.
- Council clearance of concepts will involve presentation and discussion of each concept.
- In Phase 2 planning and during planning for a second phase of support for existing programs, Common Fund Working Groups will conduct outreach to external and intramural scientists as appropriate for the particular scientific area. Investigators who are working in the field will be invited to articulate the current status of the field and to identify challenges and opportunities. Potential users of the data, resources, etc. that the program would develop will also be engaged. Attempts will also be made to engage potential skeptics of the program.

Clarify the criteria for new Common Fund programs, including criteria for urgent programs and those that involve allocation of funds to the NIH intramural program.

Due to the subjectivity of Common Fund criteria, iterative discussion is required to clarify the criteria with any group or individual who is considering new concepts. Programs that address urgent needs should meet the same criteria; the timeline for implementation of these programs is compressed, but they should otherwise be identical to other Common Fund programs. Programs that involve allocation of funds to NIH intramural investigators without competition with extramural investigators also must meet these criteria.

- During the earliest phases of articulating concepts and during planning for a second phase of support for existing programs, OSC staff will be available to meet with NIH staff and external scientists to help define the Common Fund criteria. OSC staffing will be adjusted to allow more time for these discussions in Phase 2 as well, with the expectation that OSC will be a full partner with lead ICs as goals for new programs are established.
- A small group of IC Directors will be engaged both before a concept goes to the Council for clearance and during Phase 2 planning. These small groups will be composed of volunteers who express a willingness and interest in helping to develop the shape and scope of the new programs. Their discussions will help to clarify criteria for new programs with the Working Groups and will ensure that the program proposals are broadly relevant.

- The decision to implement a given set of goals through intramural-only funding is a strategic decision and will be made as part of the Phase 2 planning process. Review of specific strategies to achieve the scientific goals will be conducted by DPCPSI, a small group of IC Directors, the NIH Principal Deputy Director, and the NIH Director at the end of Phase 2 planning. The criteria for considering allocation of funds to the NIH intramural program without competition were established by the NIH Steering Committee and will be discussed with all Common Fund Working Groups during Phase 2 planning.

Provide opportunities for richer or increased participation by the IC Directors and the Council as concepts are developed and selected

The Council recommended that NIH reconsider the processes through which IC Directors provide input on the goals and priorities for potential new and continuing programs. This reflects a strong endorsement that the Common Fund should focus its programs on shared priorities.

DPCPSI led a discussion of these Council recommendations with the IC Directors at an NIH Leadership Forum in October 2014. The plan below reflects input received during that discussion.

OSC will engage all of the IC Directors in program planning and decision making in two ways: 1) in regularly scheduled meetings of the IC Directors, DPCPSI will lead high level discussion of funds available, planning processes, and concepts being considered. This will allow all of the IC Directors to be kept apprised of Common Fund programs and to provide a general sense of enthusiasm or concern. 2) Detailed discussions will be held as concepts or programs face a major decision point. Questions that will be considered in this type of discussion include: Is a given concept ready to be discussed/cleared by the Council? Is a given Phase 2 proposal ready for discussion with the NIH Director? How could the proposal be adjusted? What is the appropriate size and scope of the program compared to other priorities? As ongoing programs develop plans for a second stage of support, are the plans likely to create the need for long-term, dedicated funds from the ICs? How should the second stage of Common Fund support address the long-term support of the science? Concepts will include a rough estimate of the size and scope of the program. After a concept has been cleared and Phase 2 planning is underway, it will be reviewed with the Council at a subsequent meeting with further input to shape the final program plan.

Enhance partnership between OSC and the ICs through improved working relationships, communication, and transparency as concepts are formed and selected

- The Council's recommendation for enhanced partnership between OSC and the ICs was accompanied by a recommendation that OSC be given the resources to devote more staff effort to the planning and management processes. This recommendation will allow OSC to do the following to increase transparency and communication with IC colleagues:
 - Meet in small and large group settings with IC staff to discuss CF criteria, processes, and plans for managing programs. Engage in ongoing dialog with IC colleagues as concepts are planned and managed.
 - Devote dedicated staff time to facilitate portfolio analyses with Working Groups to ensure consistency and to ensure that program-specific questions are addressed.
 - Support orientation and team building activities with Working Group coordinators to promote idea sharing and partnership as new groups are established.

STRATEGIC PLANNING FOR FISCAL YEAR 2018 AND BEYOND

In 2015, OSC will begin a new round of Phase 1 strategic planning that incorporates the Council recommendations above. Programs that emerge from this process are expected to be implemented in fiscal year 2018, but the actual start date of each program may vary. OSC will host a meeting with external experts nominated from the ICs and from OSC, representing a broad range of scientific disciplines and career stages. Ideas generated from this meeting will be posted in an online discussion forum to allow the broader biomedical research community to provide input and to propose novel ones. Potential program concepts will also be solicited from the IC Directors, and may also arise from discussions involving NIH Leadership, Advisory Councils, or other entities providing input to NIH. OSC/DPCPSI will organize a retreat for IC Directors and DPCPSI/NIH Leadership to discuss and prioritize these concepts for new Common Fund programs. Ideas that generate the highest levels of enthusiasm will be presented to the Council for concept clearance.

ADJUSTING STRATEGIC PLANS

The strategic plan that is developed for each program before it is launched defines the end goals for the program as well as a strategy to achieve these goals. During the lifecycle of the program, the goals are held constant, but the strategy may change in response to the progress of the science. New initiatives may need to be established, supplements to awards may be needed, individual awards may need to be reduced, or the management plan for the program may need to be adjusted. Challenges and opportunities to strengthen each program are considered continuously, but this is done systematically for every program on an annual basis. This management process ensures that the programs stay on track toward their stated goals while also allowing adjustments to ensure that the impact of each program is maximized.

PLANNING FOR TRANSITION FROM COMMON FUND SUPPORT

Common Fund programs are designed to achieve a set of high-impact goals within a 5-10 year time frame. At the conclusion of each program, deliverables will either stimulate IC-funded research or will transition to support by ICs or other entities that find the resources generated by the program useful.

Transition plans are considered early in the lifecycle of a Common Fund program and these plans are reconsidered throughout the lifecycle to ensure the transition accommodates the changing needs of both the program and the external scientific community. The following Common Fund programs are currently undergoing or have undergone transition since 2013.

Bridging Interventional Development Gaps (BrIDGs) was supported by the Common Fund from fiscal year 2004 to fiscal year 2013. Initially known as Rapid Access to Intervention Development (RAID), BrIDGs provided eligible scientists with no-cost access to contractor services, such as toxicology studies, for pre-clinical therapeutics development. As of late 2014, BrIDGs had generated data to support 15 investigator-held Investigational New Drug Applications (NDAs) that have been cleared by the Food and Drug Administration. BrIDGs is now managed in NCATS.

The Building Blocks, Biological Pathways, and Networks (BBPN) program was supported by the Common Fund from fiscal year 2004 to fiscal year 2014. The BBPN program developed new technologies for studying molecular events that comprise biological pathways and networks in cells in order to catalyze studies on normal and disease-related processes. Although related work continues through other mechanisms, this program achieved its goals and materials and resources generated by this program are now being widely used by the research community. After the end of the program, one center under the

National Technology Centers for Networks and Pathways (TCNP), an initiative within the BBPN program, continued to produce resources that were cited in over 40 publications. TCNP worked with over 200 investigators to provide access to these resources. Another center had users in 27 states and 21 countries that accessed its resources and it assisted in approximately 100 projects. This program exemplifies the research enabling goal of many Common Fund programs.

The NIH Medical Research Scholars Program is a 12-month residential program that provides training for the next generation of clinician-scientists to learn about translational research, from the bench to the bedside and back to the bench. From 2004 until 2013, a similar program called the Clinical Research Training Program (CRTP) was supported by the Common Fund. Building upon lessons learned from the CRTP program, the MRSP program was launched in fiscal year 2014 with support from the Common Fund. Common Fund support for MRSP facilitated the transition of the program to a public-private partnership model, and it is now supported through the NIH Clinical Center. The final evaluation of the Common Fund-supported CRTP/MRSP program showed that over 60% of the alumni cohort that responded was engaged in research.

The Molecular Libraries and Imaging program offered biomedical researchers access to the large-scale screening capacity necessary to identify small molecules that can be optimized as chemical probes to study the functions of genes, cells, and biochemical pathways associated with normal health and several diseases. These molecules are used by researchers in the public and private sectors to validate new drug targets which, ultimately, shortened the drug-development pipeline. Multiple probes initiated in this program are now in various stages of clinical trials. Resources such as PubChem (now managed by the National Library of Medicine's National Center for Biotechnology Information) and the Small Molecule Repository (renamed the Small Molecule Resource, now managed by NCATS) will remain in use. The Probe Production Centers that were established to screen the probes will remain active since their services continue to be used by the broader scientific community. These collaborations are supported by investigator-initiated research grants (R01s) and other NIH funding mechanisms, and by the NCATS Intramural budget. The Molecular Libraries program was supported by the Common Fund from fiscal year 2004 to fiscal year 2014. During that time, small molecule screening for research probes became a standard approach to better understand protein functions and to identify new therapeutic targets. The Common Fund program contributed substantially to this transformation of research practice.

Patient-Reported Outcomes Measurement Information System (PROMIS) addressed a need in the clinical research community for a rigorously tested patient reported outcome (PRO) measurement tool. This tool utilizes recent advances in information technology, psychometrics, qualitative, cognitive, and health survey research to measure PROs. PROs such as pain, fatigue, physical functioning, emotional distress, and social role participation have a major impact on quality-of-life across a variety of chronic diseases. PROMIS is rapidly becoming the global standard tool for quantifying patient reported outcomes in human research and clinical care. The PROMIS program exemplifies the transformative nature of Common Fund programs because it has changed the way clinicians assess outcomes – which are now easily quantified and reproducible. The National Cancer Institute (NCI) will maintain part of the PROMIS infrastructure under the new name PCORR: Person-Centered Outcomes Research Resource. This NCI activity will ensure that the core infrastructure is supported; a fee-for-service model will be used to pay for support for individual projects. PROMIS was supported by the Common Fund from fiscal year 2004 to fiscal year 2014.

The Structural Biology program pioneered new methods for determining the three dimensional shape of membrane-bound proteins, catalyzing this field of research and contributing to the 2012 Nobel Prize in Chemistry. As the breakthrough methods and techniques developed by the Structural Biology program are widely adopted, they will enhance research supported by NIH ICs and other funding entities. This program was supported by the Common Fund from fiscal year 2004 through fiscal year 2013.

APPENDIX A: THE COMMON FUND BUDGET

Dollars in Millions	FY 2013 Actual	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget Request
Common Fund	\$513.48	\$531.17	\$545.64	\$565.64
Common Fund Percent of NIH Labor/HHS Funding ¹	1.77%	1.78%	1.81%	1.82%

¹Excludes mandatory funding for the Type 1 Diabetes Research program and funding appropriated through the Interior, Environment, and Related Agencies Appropriations Bill for the NIEHS Superfund Research and Worker Training Program.