THE 2014 REVIEW OF PROCESS AND MANAGEMENT OF THE NIH COMMON FUND: REPORT BY THE COMMON FUND EVALUATION WORKING GROUP

June 19, 2014

ACKNOWLEDGEMENTS

The activity of the Common Fund Evaluation Working Group (CFEWG) that resulted in the formulation, assembly, and publication of this report could not have taken place without the dedicated commitment and hard work of the staff and contractors of the National Institutes of Health (NIH). We are deeply grateful to all of our colleagues on the CFEWG, who brought their expertise and informed counsel to teleconferences, interviews, and face-to-face meetings, and who contributed significant time and effort to the development and writing of this report. We also wish to thank the NIH Institute and Center Directors and their staff, who took the time to prepare for their interviews in advance, and who fully engaged in discussions with CFEWG members. We are very grateful to the Director of the Office of Strategic Coordination (OSC) and her staff for providing full transparency and support by participating in teleconferences, answering queries, and furnishing documents that helped the CFEWG understand the past processes of the Common Fund (CF). Our interactions made it clear that the OSC is fully committed to improving and strengthening the CF and ensuring its success. We are indebted to the several hundred NIH staff members who read, answered, and returned the 2014 NIH CF Evaluation Survey. Their responses, observations, and comments deepened our understanding of the CF and provided nuanced insight into the ways in which perceptions of the CF have changed since the 2005 NIH CF Evaluation Survey. Finally, our thanks go to the Windrose Vision staff, who provided logistical support, carefully crafted teleconference summaries, prepared supporting documents, and offered continuous assistance to the CFEWG throughout. Without their constant attention and hard work, the CFEWG would never have been able to fulfill its mandate.

TABLE OF CONTENTS

ACRONYMS, ALPHABETIZED

ACD	Advisory Committee to the Director
BEST	Broadening Experiences in Scientific Training
BO	Budget Officer
BPOC	Budget Point of Contact
CF	Common Fund
CFEWG	Common Fund Evaluation Working Group
CGMO	Chief Grants Management Officer
CoC	Council of Councils
CRTP	Clinical Research Training Program
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
EMPC	Extramural Program Management Committee
EO	Executive Officer
ERP	Extramural Research Program
ESC	External Scientific Consultants
ESP	External Scientific Panel
FOA	Funding Opportunity Announcement
FTE(s)	Full-time employee(s)
GMO	Grants Management Officer
GTEx	Genotype-Tissue Expression
GuLF	Gulf Long Term Follow-up
HMP	Human Microbiome Project
ICs	Institutes and Centers
IHEC	International Human Epigenome Consortium
IRP	Intramural Research Program
iPSCs	Induced pluripotent stem cells
$KOMP^2$	Knock out Mouse Phenotyping
LINCS	Library of Integrated Network-Based Cellular Signatures
ML	Molecular Libraries and Imaging Program
NCBI	National Center for Biotechnology Information
NCATS	National Institute for Advancing Translational Science

NCBC	National Centers for Biomedical Computing
NHGRI	National Human Genome Research Institute
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIDA	National Institute on Drug Abuse
NIDDC	National Institute on Deafness and Communicative Diseases
NIDDK	National Institute of Diabetes and Digestive and Kidney Disorders
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH CRM	NIH Center for Regenerative Medicine
NIMH	National Institute of Mental Health
OD	Office of the Director
OSC	Office of Strategic Coordination
ORIP	Office of Research Infrastructure Programs
P&E	Planning and Evaluation
PI	Principal Investigator
PROMIS	Patient-Reported Outcomes Measurement Information System
RFI	Request for Information
RFP	Request for Proposal
RM	NIH Roadmap for Medical Research
RMS	Research Management and Support
TRA	Transformative Research Awards
WG	Working Group

EXECUTIVE SUMMARY

Common Fund Evaluation Working Group Charge

The National Institutes of Health (NIH) Roadmap for Medical Research (RM) was launched in 2004 as a new way to plan and support science, with the goal of funding the most compelling initiatives that the NIH should pursue and that would make the biggest difference in biomedical research. The ensuing initiatives cut across NIH Institutes and Centers (ICs) and integrated multiple disciplines. The NIH Reform Act of 2006 (Public Law 109-482) authorized and appropriated funds for the Common Fund (CF) to support the trans-NIH initiatives funded through the RM. The Reform Act created the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the NIH Office of the Director (OD) to lead strategic planning for, and coordinate implementation of, CF programs with the NIH ICs. The Office of Strategic Coordination (OSC), an office within DPCPSI, administers the CF. The Reform Act also required that CF-supported projects specify milestones and goals, include timeframes for funding, and ensure consideration of proposals from new investigators. To implement the CF, the NIH developed principles for prioritizing potential CF programs, focusing on those that are transformative, synergistic, catalytic, cross-cutting, and unique, and require a high level of coordination.

The first decade of the RM/CF has produced over 30 programs and experimented with strategic planning processes to identify research topics and develop and manage programs. In 2013, the NIH Director established a Common Fund Evaluation Working Group (CFEWG) to evaluate the principles and processes used to manage the CF, review evaluative information from a subset of CF programs to assess the impact of CF-supported science, and provide recommendations on how to optimize the success and impact of the CF as the program enters its second decade. The NIH asked the CFEWG to provide recommendations to be considered by the NIH Council of Councils (CoC) at their meeting on June 20th, 2014.

The CFEWG's overarching goal was to assess and advise on the processes used to manage the CF, including those used to plan and implement/oversee programs, by examining two major questions:

1. Are planning processes optimal for identifying program areas that meet the CF criteria?
2. Are management/oversight processes optimal for achieving program goals?

The CFEWG carried out its charge through a close examination of two fundamental CF processes: strategic planning and management. To assess these two processes, the CFEWG reviewed documents provided by OSC, the CF Handbook, and results from 2005 and 2014 NIH CF Evaluation Surveys. The CFEWG also conducted interviews with Directors of ICs, OSC Staff, Working Group (WG) members, Grants Management Officers (GMOs), Budget Points of Contact (BPOCs), Executive Officers (EOs), Planning and Evaluation (P&E) Officers, and members of the Extramural Program Management Committee (EMPC) of lead ICs of CF

programs. Summaries of the CFEWG findings on CF strategic planning and management processes are below.

Common Fund Strategic Planning Process

Strategic planning entails identification of broad scientific areas representing trans-NIH challenges and opportunities that are best addressed through finite, short-term, goal-driven programs. Once identified and cleared for further development, concepts are then refined into well-defined CF program initiatives. The process is initiated annually and lasts approximately 18 months.

Unlike the development of other traditional research projects within pre-defined scientific areas at the NIH, strategic planning for a CF project is separated into two phases to allow sufficient time for thoughtful input and informed discussion. In Phase 1, broad concepts incorporating scientific needs and opportunities are identified. In Phase 2, successful concepts are refined into specific, well-defined initiatives ready for implementation.

The NIH CoC, an external advisory panel to DPCPSI and the NIH Director, is engaged at the interface between Phase 1 and Phase 2 in an evaluative process called "concept clearance." This process determines which broad ideas are further considered as CF programs. Concepts cleared by the CoC are discussed with the NIH IC Directors and prioritized by DPCPSI and NIH Directors, who then identify those concepts that should move to Phase 2 planning.

Phase 1 Planning

Our analysis of ideas considered for new CF programs between 2002 and 2013 revealed that most were solicited from ICs or from meetings with experts in the extramural research community. We were not able to determine objectively which solicitation method was most informative, although the consensus opinion among IC Directors and staff interviewed was that the most fundable ideas arose from the ICs. There was broad agreement that ICs play a very important role in the gathering of ideas for CF programs.

Our analysis also revealed numerous outreach efforts to engage the broader research community to identify CF ideas. Of these, external meetings with invited scientific "thought" leaders and experts were the most effective in generating ideas that meet the criteria for becoming a CF program. On the other hand, Requests for Information (RFIs) and open public meetings were thought to be less effective. Finally, opinions were offered that it may be difficult to find broad support among ICs for programs that arose from recommendations from the Advisory Committee to the Director (ACD), because they emerge independently of input from the ICs.

Broader appreciation and "buy-in" to the significant financial investment in the CF can increase if more efforts are made to increase awareness about the CF and inform the scientific community of the scientific value and accomplishments of CF programs. Because paradigm-shifting ideas

are rare, supporting only ideas that have majority buy-in may result in funding programs that are less disruptive and have the potential to be less innovative than truly unique and transformative ideas that might initially garner only limited acceptance but have the potential to make visionary scientific advances.

Strategies for soliciting new ideas that are appropriate and relevant to the CF could be improved and refined. Although different approaches have been used successfully to solicit ideas from year to year, there seems to be a need for more creative ways to generate innovative ideas that are relevant to the CF mission. Irrespective of the methods used to solicit and generate ideas for CF programs, our findings identified the importance of ensuring consistency, clarity, and transparency in the decision-making and prioritization processes used to determine which ideas are sent forward for CoC clearance.

The need for continued emphasis on communication and feedback persists once DPCPSI decides which ideas to send forward for CoC clearance. Those submitting ideas could benefit from additional guidance in preparing their submissions so that they address the criteria used to assess whether ideas are appropriate for the CF. Therefore, clearly defining and articulating criteria for evaluating and deciding how ideas succeed or fail to be submitted for CoC clearance would be highly beneficial.

IC program staff are already attuned to thinking ahead and engaging in long-term planning within their respective ICs. Therefore, generating ideas for CF projects becomes a compilation of ideas that does not require an extensive time commitment. However, gathering ideas from the public or through meetings with scientific experts takes more time to coordinate. For this reason the nine-month timeframe seems adequate and appropriate, although there are concerns that prolonged planning periods could negatively impact the ability to rapidly advance a topic with a time-sensitive component.

Phase 2 Planning

Goals and milestones for programs are developed during Phase 2. The ability to develop clear goals for a particular CF program is often related to the focus of the program itself and the quality of the portfolio analysis. If a CF program is more specific and focused from the outset, the goals are more clearly articulated. When a program does not have clearly articulated goals, the program struggles and it can take a few years to get back on track. Therefore, all potential CF programs can benefit from clear and realistic goals and milestones.

Nine months was generally considered sufficient to conduct an adequate portfolio analysis, and to solicit additional input during Phase 2. While processes for providing input have been established, there is a need for enhanced levels of communication and to provide regular feedback on the progress and development of CF proposals to ICs that are not directly involved in the development of a specific CF program.

Rapidly emerging challenges or opportunities may necessitate the development of new CF programs within weeks rather than months. Although the Gulf Long Term Follow-up (GuLF) program is an example of this sort of program, no formal process is in place to respond to similar future crises. This should be addressed.

Unlike awards to extramurally-funded programs, Intramural Research Programs (IRPs) funded by the CF are not similarly reviewed. When launching a CF program as an IRP, NIH should articulate the unique patient populations and resources that justify investment by the CF. Besides emphasizing what expertise resides within the NIH, it would be useful to also provide a concrete framework, based on timeliness and the need for rapid implementation, for deciding when programs should be implemented through the IRP. Further, there appears to be no clear definition about what constitutes a rapid response to an "emergency concept," or how an emergency concept can be distinguished from other "high-priority" concepts. No process exists for determining whether an emergency concept is relevant to the CF mission. Therefore, the design of the "regular" 18-month CF strategic planning process is not compatible for emergency situations that might represent trans-NIH interests.

Phase 1/Phase 2 Planning: Relationships and Level of Interaction

Within the strategic planning process itself, three themes emerged as needing attention and refinement. With regard to clarity and understanding, changes naturally occurring as a result of evolution of the strategic planning process over the last decade have caused some confusion leading to a decrease in transparency in the overall process. Enhancing the level and regularity of *communication and feedback* would be well received and appreciated, resulting in even greater participation in the CF planning process. Also, the variability in budgets available for CF projects during the last several years has created challenges to the strategic planning process. Working towards *consistency in funding availability* from year to year will contribute to a better appreciation for the CF. Finally, and not surprisingly, a successful idea that becomes a CF project promotes satisfaction by NIH staff with the CF. Another important theme is *feedback.* Maintaining enthusiasm for the CF and supporting the continued submission of concept proposals requires that researchers receive feedback on what proposals did not succeed, what made them less competitive, and the decision-making process used to make the determination.

Decision-making is a key element of the strategic planning process, and one that requires transparency, input, and active and informed engagement and involvement by all stakeholders. This principle has been observed to a varying extent. Working to ensure that all NIH staff have a full understanding of these processes would enhance the transparency of decision-making. Because of their scientific expertise and experience, IC Directors should be afforded an even greater opportunity to be fully included in vetting ideas. There is a clear consensus that the ultimate decision should remain that of the Director; however, more input from the IC Directors can add substantial value to the decision-making process.

Nonetheless, tactical input from key leadership is needed to make the most informed decisions. For example, the IC Directors could serve a direct, advisory role to the NIH Director on which concepts cleared by CoC are ultimately decided to be funded as CF projects. Establishing regular interactive communications would be very informative in this part of the decision-making process.

Finally, the extent and depth of interactions between OSC and ICs staff have evolved and changed considerably over time. Clearly, the level of interactions between OSC and IC staff is critical to good, bidirectional communication on CF projects. There is general consensus that the level and content of interactions vary, and this remains a challenge. The restructuring of the OSC and the increase in CF staff beginning in 2007 have begun to address this concern, but more help is needed.

The CFEWG developed 21 recommendations for improving and enhancing strategic planning for CF programs.

Recommendations for Phase 1 Planning

RECOMMENDATION 1: *Enhance efforts to educate and inform the scientific community about the purpose and goal of the CF.*

RECOMMENDATION 2: *Revise the solicitation process in Phase 1 planning to broaden the diversity and scope of input without overburdening the process with ideas that are irrelevant and inappropriate.*

RECOMMENDATION 3: *Evaluate what has worked well, and what has not, in the process for soliciting ideas and concepts internally from ICs and externally from participants at expert meetings, and improve the process where possible.*

RECOMMENDATION 4: *Clearly articulate the purpose and goal of the CF to participants in expert meetings to maximize the relevance of ideas generated.*

RECOMMENDATION 5: *Enhance and refine the existing Phase 1 planning processes to maximize the effectiveness of gathering input from external and internal sources during the allotted nine months, including developing different approaches and mechanisms for external meetings of experts.*

RECOMMENDATION 6: *Draft guidelines that formalize the process for articulating and developing ideas so that they are presented in a "Common Fund-able" way.*

RECOMMENDATION 7: *Establish other approaches, including a CF pilot project process, that could enhance flexibility in the CF strategic planning process for determining which ideas warrant additional investment.*

RECOMMENDATION 8: *Establish mechanisms that allow more flexibility for managing the development of concepts and refining concepts into program proposals.*

Recommendation for Rapid Planning for Urgent Needs

RECOMMENDATION 9: *Define criteria and establish a standard operating procedure for rapid responses to emergency challenges and opportunities that are consistent with the CF purpose and goal and justify CF investment.*

Recommendation for CoC Review

RECOMMENDATION 10: *Review and revise procedures by which the CoC reviews and assesses concepts for clearance, including developing and articulating guidelines for the criteria used to eliminate or modify ideas before being sent to the CoC for clearance.*

Recommendations for Phase 2 Planning

RECOMMENDATION 11: *Establish and articulate the process by which cleared concepts develop and progress into CF programs.*

RECOMMENDATION 12: *Ensure sufficient time and resources are available for comprehensive and consistent portfolio analyses.*

RECOMMENDATION 13: *Clearly define and clarify the roles and responsibilities of OSC and WG members in Phase 2.*

RECOMMENDATION 14: *Provide more opportunities for IC Directors and the CoC to enable sufficient feedback on concepts that are being developed in Phase 2*.

RECOMMENDATION 15: *Ensure sufficient representation on the CoC or a subcommittee of CoC to enable all ICs to participate in Phase 2.*

RECOMMENDATION 16: *Ensure greater transparency/clarity surrounding the process by which programs exit Phase 2 as funded CF programs*.

RECOMMENDATION 17: *Streamline and clarify the steps for selecting Phase 2 ideas and developing them into program proposals.*

Recommendation for Intramural-only CF Programs

RECOMMENDATION 18: *Develop a concrete framework for when a program is suitable for an intramural-only program, including further clarifications regarding the criteria.*

Recommendations for Communication and Input

RECOMMENDATION 19: *Develop a mechanism to increase IC Directors' input to the OD in decision-making on CF programs.*

RECOMMENDATION 20: *Improve communication and working relationships between OSC and IC staff developing CF programs.*

RECOMMENDATION 21: *Communicate as early as possible the availability of funds to support new CF programs.*

Common Fund Management Process

All CF programs follow a similar program structure and management, with oversight provided by an OSC Program Director. This creates a uniform way to capture and present data across all CF programs. Once a CF concept is approved for Phase 2 planning, a request is sent to IC Directors asking for additional members to join the existing WG for the CF program. The staff largely comprise those involved in extramural programs. WGs oversee the development and implementation of CF programs and identify emerging issues related to their area/topic that may warrant revisions to their program. The WG oversees the management of CF programs in both the pre- and post-award phases, and communicates regularly with its assigned OSC Program Director so that OSC remains informed about progress towards goals and milestones, particularly if there are any updates to these targets. The OSC asks each WG to complete an annual progress report at the start of each fiscal year.

The CFEWG obtained input from many sources to assess whether expectations for programs are clearly articulated in funding announcements, program kick-off documents, websites, and program materials; and whether programmatic goals and responsibilities are clear. In interviews, OSC staff commented that the WGs that developed strong Funding Opportunity Announcements (FOAs) and established effective working group structures also tended to clearly articulate the goals and responsibilities of the PIs and the WG. These WGs had greater likelihood of success, while other WGs and CF programs did not have the same level of clarity and were less effective overall. Close examination of CF programs for which program summaries were provided showed that there was uneven performance in meeting the original goals and milestones set forth in the FOAs. OSC staff voiced the opinion that when a program does not have clearly articulated goals, the program struggles.

During interviews, both WG members and OSC staff made two important points. First: there should be an *orientation of the WG members* by the OSC CF Program Director, who will facilitate all phases of the CF program management. Interviewees also suggested including experienced WG members in the orientation, as a mechanism for sharing lessons learned in other CF program management. Second: the *clarity and timeliness of communication* between the

WGs and the OSC Program Directors needs improvement. Both WG members and OSC staff were less than satisfied. OSC staff indicated they do not routinely communicate to WGs the decisions that affect WG management and budget issues.

The evaluative processes defined for CF programs are meant to provide critical assessment throughout the program's lifespan. Interviews with WG members and OSC staff showed that it was clear to all that the Annual Progress Reports mandated by OSC were important to the CF program, as the reports addressed the program's strengths and weaknesses and allowed the WG to make the case for changing priorities and/or reallocating resources. However, some WG members commented that there was lack of clarity about the expectations of OSC Program Directors with regard to the Annual Progress Report. Discussions between OSC Program Directors and WGs were needed to help them develop reports that worked for their program. This should be clearly articulated in the CF Handbook. OSC staff mentioned that poorly prepared Annual Progress Reports do not incur any negative consequences, and so some WGs do not have incentives to do them well. Also, WG members commented that there was sometimes an imbalance between conducting innovative science and micromanaging progress and milestones.

Management processes for IRP-only programs are not as well developed relative to other CF programs. The CFEWG found that the CF Handbook does not provide a detailed process for the management of these programs. Further, the success of IRP-only programs, as measured by achievement of their goals and milestones, does not appear to be as high compared to that of other CF programs.

Interviews with both WG members and OSC staff showed that interactions between ICs and OSC are collaborative and work well. However, CF program staff and ICs do not necessarily know what OSC Program Directors expect in terms of interactions with OSC during the course of the funded program. WG members commented that OSC roles are not clearly defined, and that the organization of OSC in relation to the WG is not clear.

Responses to the 2014 CF Evaluation Survey indicated that the WG structure works well and is effective for meeting the scientific goals of the program. However, survey respondents did not feel that OSC guidance on forming WGs was sufficient, or that OSC policies and procedures for managing WGs are clear. Survey respondents who were WG members commented that the success of the WG could be attributed to strong leadership and excellent organization, and that being part of WGs had been rewarding.

Overall, responses from both the 2014 CF Evaluation Survey and interviews with IC Directors and WG members describe the value of the CF programs in terms of: addressing science that could not be tackled by a single IC; benefiting the scientific missions of the ICs; increasing the likelihood of collaborative, high-impact trans-NIH programs and activities; and encouraging a culture of change, shared resources, cooperation, and collaboration among ICs.

Interviews with IC Directors showed that Directors who are strongly involved with and lead CF programs receive adequate information about those CF programs. However, those who participate without actively leading CF programs, and those who are not involved in a CF program, did not feel that they received adequate information, or that they had substantive input into the CF decision-making process. Both survey results and interviews showed that WG members are not fully satisfied with the breadth and level of information they receive from senior IC management about CF programs. It appears that the level of dissatisfaction expressed by WG members increases with distance on the organizational chart from senior IC management. This suggests that CF program information is flowing to IC senior management, but is not being effectively transmitted to the rest of the organization.

The CFEWG developed 26 recommendations for improving and enhancing management of CF programs. It is recognized that the implementation of some recommendations, both in this and the previous section, may require a reallocation of or additional OSC resources.

Recommendations for FOAs and Kick-off meeting

RECOMMENDATION 22: *Provide a comprehensive template for essential elements in CF program FOAs.*

RECOMMENDATION 23: *Include GMOs early in the process of developing FOAs.*

RECOMMENDATION 24: *Include information in the FOAs about how the CF is funded.*

RECOMMENDATION 25: *Provide links to relevant background documents in FOAs.*

RECOMMENDATION 26: *State goals and milestones explicitly in FOAs and kick-off meetings.*

RECOMMENDATION 27: *A kick-off meeting for all new CF programs should be held with funded PIs, NIH staff, Steering Committee members, and external Scientific Advisory Committee members. The program's overall organization should be described in the CF Handbook to inform participants about the program.*

Recommendations for CF WGs and OSC Program Directors

RECOMMENDATION 28: *OSC Program Directors should educate WGs about the need for and use of Annual Progress Reports.*

RECOMMENDATION 29: *The CF WGs should review goals and milestones at least annually.*

RECOMMENDATION 30: *Define the working relationships and interactions between OSC Program Directors and CF WGs.*

RECOMMENDATION 31: *OSC should improve guidance on forming WGs.*

RECOMMENDATION 32: *Establish clear mechanisms for communications between CF PIs and their respective WGs.*

RECOMMENDATION 33: *Encourage all WG members to use the CF Handbook as a guide for program management.*

RECOMMENDATION 34: *Provide an orientation on WG structure for new CF programs.*

RECOMMENDATION 35: *Gather and disseminate CF "best practices" for the benefit of all WGs.*

RECOMMENDATION 36: *Identify CF mentors who have successfully managed CF programs to guide new CF WGs.*

RECOMMENDATION 37: *Provide a CF Handbook to grantee PIs to inform them of CF program planning and management, or a version focused on information relevant to the PIs.*

Recommendations for Evaluation of CF Programs

RECOMMENDATION 38: *Clearly define evaluation plans at the outset of CF programs.*

RECOMMENDATION 39: *Conduct evaluation reviews prior to the end of the first phase of a CF program.*

RECOMMENDATION 40: *OSC should conduct annual CF program management reviews to provide feedback to WGs on management of the CF program and whether the goals and milestones are being achieved.*

Recommendation for Intramural-only CF Programs

RECOMMENDATION 41: *Justify the need for intramural-only CF programs, and establish clear processes for all aspects of intramural-only CF program management.*

Recommendations for Communication and Input

RECOMMENDATION 42: *Explore ways to leverage the benefit of trans-NIH cooperative relationships developed through CF WGs to improve interaction between ICs and non-CF projects.*

RECOMMENDATION 43: *Establish incentives to drive even greater participation and engagement in CF programs by IC Directors and staff across the NIH.*

RECOMMENDATION 44: *Provide regular updates on CF programs to IC Directors: for example, quarterly updates at the IC Directors' meeting.*

RECOMMENDATION 45: *Provide regular updates on CF programs to the NIH community.*

RECOMMENDATION 46: *Conduct a study to identify the best vehicle for communication about CF programs.*

RECOMMENDATION 47: *Improve communication about CF programs by IC Directors.*

COMMON FUND EVALUATION WORKING GROUP CHARGE

At the National Institutes of Health (NIH) Council of Councils (CoC) meeting on September 24, 2013, the Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) established the Common Fund Evaluation Working Group (CFEWG) to evaluate the strategic planning and management processes of the NIH Common Fund (CF). The NIH asked the CFEWG to provide recommendations to be considered by the NIH CoC at their meeting on June 20th, 2014.

The CFEWG was charged with addressing two overarching questions and specific related questions:

1. Are planning processes optimal for identifying program areas that meet the CF criteria?
2. Are management/oversight processes optimal for achieving program goals?

Strategic Planning Process

1. *Are planning processes optimal for identifying program areas that meet the Common Fund criteria?*

For Phase 1 Planning:

I. What are the best methods of engaging the broader scientific community?
II. Do the concepts, as currently written at the end of Phase 1, allow effective review by the CoC? Should the format and content of the concepts be adjusted? Should DPCPSI more stringently filter concepts that are not clearly articulated and ask the CoC to review only those concepts for which there is enthusiasm?
III. Is nine months for Phase 1 planning an appropriate time frame?
IV. Should an alternate process be developed for rapid planning for "emergency concepts"?

For Phase 2 Planning:

V. Do Phase 2 processes result in clearly articulated goals and expected milestones?
VI. Is nine months an appropriate timeframe for Phase 2 planning?
VII. Do Directors of Institutes and Centers (ICs) and the CoC have appropriate levels of input to guide the development of Phase 2 proposals?

For both Phase 1 and Phase 2:

VIII. What should the process be for planning intramural-only programs?

IX. What are the attitudes and level of understanding of NIH staff toward the current planning processes, including how decisions are made? What difficulties in the process can staff identify to facilitate greater satisfaction and engagement?

Management Process

2. Are management/oversight processes optimal for achieving program goals?

Questions pertaining to interactions with awardees:

I. Are expectations for programs clearly articulated in funding announcements, program kick-off documents, websites, and program materials? Are the goals and responsibilities clear?
II. Are evaluative processes sufficient to provide critical assessment throughout the program's lifespan?
III. Are goals and milestones met?
IV. Are management processes flexible and adaptive to changing scientific landscapes?
V. What should the process be for management of intramural-only programs?

Questions pertaining to intra-NIH interactions:

VI. Are interactions between the Office of Strategic Coordination (OSC and ICs working well?
VII. Is the WG structure meeting the management and oversight needs of the programs?
VIII. Are the roles and responsibilities of WG members clear?
IX. Is the value of the program worth the effort?
X. Do IC Directors get appropriate amounts of information about CF programs and at an appropriate frequency?
XI. Does participation by IC staff on CF WGs enable efficient information exchange with IC Directors, IC Councils, other IC staff, and IC research communities?

Common Fund Evaluation Working Group Leadership and Subgroups

Co-Chairs and Members

The CFEWG consisted of six scientists: three members of the CoC, and three members from External Scientific Panels (ESPs) of CF programs who are familiar with CF Management and oversight practices.

CoC members:

- K. C. Kent Lloyd, D.V.M., Ph.D.
- Janice Clements, Ph.D.
- Steven DeKosky, M.D.

ESP Members:

- Marisa Bartolomei, Ph.D.
- Samuel Gerritz, Ph.D.
- Martin Friedlander, M.D., Ph.D.

Drs. Kent Lloyd and Janice Clements were asked to Co-Chair the CFEWG and oversee all its activities. The CFEWG's membership roster and member biographies are available in Appendix 1 and Appendix 2, respectively.

Subgroups

The CFEWG as a whole reviewed the relevant background information and data to gain a comprehensive understanding of all CF strategic planning and management practices. The CFEWG also participated as a group in discussions, interviews, and analyses that informed the findings of the evaluation. The CFEWG then decided to divide into two subgroups to develop and write the report. Dr. Lloyd led the Strategic Planning section of the report, and Drs. Friedlander and DeKosky served in this subgroup. Dr. Clements led the report's Management and Oversight section, and Drs. Bartolomei and Gerritz served in this subgroup. The CFEWG then came together to discuss the subgroups written sections, reviewed the entire assembled report, and agreed on the final compiled recommendations.

Meetings

The CFEWG met 14 times between September 2013 and June 2014, which included two in-person meetings and 12 teleconferences. The two in-person meetings were on January 30, 2014 and May 15, 2014. The 14 teleconferences were held from November 19, 2013 to June 17, 2014. Dr. Betsy Wilder, Director of the OSC, and Mr. Scott Jackson, OSC Operations Team Leader, served as the Federal Designated Officials. The list of meetings can be found in Appendix 3.

Timeline of Major Activities

Activity	Timeline
CFEWG established at the CoC meeting	September 24, 2013
Kick-off meeting with all CFEWG members	November 19, 213
Bi-weekly conference calls to review CF materials	November 19, 2013 – June 17, 2014
Face-to-face meeting	January 30th, 2014
Interviews with NIH staff	January 30th – February 27th
Online 2014 Common Fund Survey for NIH staff	February 27th- March 17th
Face-to-face meeting	May 15th, 2014

Evaluation Approach

The CFEWG reviewed documents, conducted interviews (e.g., IC Directors, NIH staff, etc.), and reviewed results of the 2014 NIH-wide CF Evaluation Survey to gather background information, generate findings, and develop recommendations. A description of each method is below.

Document Reviews

For each evaluation question, relevant documents were provided to the CFEWG in advance of the conference calls, so that group members could review beforehand and discuss the documents related to the questions on the agenda for that meeting. The documents provided CFEWG a better understanding of the strategic planning activities and processes used to manage programs. Examples of documents reviewed to address the strategic planning questions included: methods used to solicit ideas from the ICs and extramural community; concepts reviewed by the CoC; and a description of the evolution of concepts that resulted in CF programs.

To address the management questions, five programs were chosen to illustrate how initiatives were organized, milestones were set and adjusted, progress was assessed over time, and transition out of the CF was planned. The programs selected were Molecular Libraries (ML), the National Centers for Biomedical Computing (NCBC), Patient Reported Outcomes Measurement Information System (PROMIS), Human Microbiome project (HMP), and Epigenomics. The summaries for each program included goals and milestones, the evolution and history of each program, outputs, and outcomes. The list of documents that addressed each evaluation question is in Appendix 4.

Interviews with the Directors of NIH Institutes and Centers

DPCPSI invited all the Directors of the 27 ICs to participate in interviews. Eleven Directors agreed to be interviewed by the CFEWG. Eight interviews were conducted face to face, and three via teleconference. For the purpose of analysis, the ICs represented in the interviews were categorized into three groups based on the ICs' annual budget for 2014: small (budget less than $800 million); medium (budget between $801 million and $1.8 billion); and large (i.e., budget greater than $1.8 billion). The total representation was six small ICs, four medium ICs, and one large ICs.

Group Interviews with NIH Staff

Five group interviews with NIH staff were conducted: three with members of WGs for CF programs, and two with OSC staff and Program Directors. A total of 30 NIH staff members were interviewed; interviewees were members of 20 CF program WGs. The following CF programs were represented: NCBC; Building Blocks, Biological Pathways and Networks; Enhancing the Diversity of the NIH-Funded Workforce; Epigenomics; Extracellular RNA Communication;

Genotype-Tissue Expression (GTEx); Global Health; Health Care Systems Research Collaboratory; High-Risk Research; Knockout Mouse Phenotyping ($KOMP^2$); Library of Integrated Network-Based Cellular Signatures (LINCS); Metabolomics; Molecular Libraries and Imaging (ML); Nanomedicine; Protein Capture Reagents; Regulatory Science; Single Cell Analysis; and Strengthening the Biomedical Research Workforce.

The first group interview occurred on January 30, 2014, and included six participants out of seven invitees. The target audience for this group included staff who were WG members of five CF programs that started in 2004 and one that started in 2008. However, the participants in the group interview were actually involved in multiple programs themselves, so that as a group they represented 12 CF programs in total. The following ICs were represented: National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Eye Institute (NEI), and National Institute of General Medical Sciences (NIGMS).

The second group interview comprised the WG members from the newer programs that started between 2007 and 2013. Six of the nine invited members were able to attend the group discussion. The interview was conducted on January 30, 2014. The six participants represented 12 CF programs, since most members were part of multiple CF programs. The participants represented the following ICs: National Institute for Advancing Translational Science (NCATS), National Cancer Institute (NCI), National Human Genome Research Institute (NHGRI), National Institute of Biomedical Imaging and Bioengineering (NIBIB), and National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK).

The interview with the third group was conducted on February 3, 2014. Thirteen members out of the 17 invited attended the group discussion, and they represented the following five ICs: NCI, NIMH, NHGRI, NIDDK, NIAMS, and NIGMS. This group was comprised of four Budget Point of Contacts (BPOCs), three Grant Management Officers (GMOs), two Planning and Evaluation (P&E) Officers, two Executive Officers, and two members of the Extramural Program Management Committee (EPMC) of lead ICs. The BPOCs and GMOs were invited based on their involvement with the financial aspects of CF programs. P&E Officers are involved in strategic planning for CF programs and sometimes are also members of WGs. EPMC members advise the NIH Director on NIH policies and procedures governing the overall administration and management of extramural research and research training. They are generally the Director of the Division of Extramural Activities of their IC, and they have an understanding of their IC's involvement in CF programs. Executive Officers address issues related to the staffing of full-time employees (FTEs) for CF programs.

The fourth and fifth groups of interviewees (five participants in all) comprised CF Program Directors and OSC staff. The interviews were conducted on February 3 and February 27, 2014.

2014 Common Fund Evaluation Survey

An online survey was developed to gather input from the following groups: IC Directors, members of the EPMC of lead ICs for CF programs, P&E Officers, WG Members of CF programs, OSC Staff, Executive Officers, BPOCs, and GMOs. The online CF survey was open from Thursday, February 27, 2014, to Monday, March 18, 2014, and consisted of the following sections:

- Overall Impression of the Strategic Planning Process
- Collaboration
- Perception of the External Community about the CF
- OSC Organizational Structure and Roles of OSC Staff
- Working Group Structure
- Satisfaction
- Grants Management Processes
- Budget Management Processes
- CF Resource Use
- Closing Questions

The survey was sent to 743 individuals across the NIH. Survey recipients were informed that their responses would be confidential. Survey respondents were directed to different sections based on their roles and level of involvement with the CF, therefore not all questions were answered by everyone. They were given approximately three weeks to complete the survey. Four reminders were sent before the survey was closed. Partial or full survey responses were received from 326 individuals, a 44% response rate ([326 respondents/743 number of individuals sent the survey] x 100). The survey responses are presented in the aggregate in this report so that opinions cannot be traced to specific respondents. The survey report is included in Appendix 5.

1. COMMON FUND STRATEGIC PLANNING PROCESS

The Congressional passage of the Public Health Service Act in 2006 reauthorized funding for the NIH and required that the NIH Director submit a funding plan to Congress. The plan was to *"...identify 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)]. In response to this reform mandate, the NIH established the Roadmap which later became the Common Fund or CF. The NIH strategy, motivated in part by a desire to change the business model that had funded prior Roadmap initiatives, was to finance the CF through an annual appropriation directly to the Office of the Director (OD), instead of using individual IC budgets, as had been done for the NIH Roadmap. A strategic planning process was established to ensure that funded CF programs catalyze, transform, and accelerate new research across the NIH spectrum.

According to statute 42 U.S.C. §§ 282(b)(7)(A), the Division of Program Coordination, Planning, and Strategic Initiatives, or DPCPSI, was charged with implementing the CF by *"...requiring as appropriate that proposals include milestones and goals for the research.*" In order to be supported by the CF, programs would have to develop milestones and goals supportive of achieving solutions to challenges that are not currently being met, rather than simply working towards a solution to an interesting problem. Timeliness was also key to the rationale for a CF program, in that some new, unique, or otherwise special technology, scientific breakthrough, and/or fundamental revelation or understanding of a biological principle had created an immediate opportunity to solve a compelling research challenge.

Thus, the essence of the CF is that it provides a strategic and nimble approach for addressing key roadblocks in biomedical research that impede both basic scientific discovery and its translation into improved human health. CF programs capitalize on emerging opportunities to accelerate progress across multiple fields, and are expected to transform health research across a broad spectrum of disciplines. Programs are intended to be catalytic in nature, providing limited-term investments in strategic areas that then stimulate further research through IC-funded mechanisms. In this context, some potential program proposals might not yet be "ready" for CF support. Alternatively, other programs that had already achieved their milestones and goals would not meet the criteria to qualify them as a CF program.

Because the CF is unique compared to other NIH-funded research, strategic planning is particularly important to ensure that ideas proposed for the support fulfill the stated objectives of the CF. Over the last 10 years the CF strategic planning process has evolved to pilot different strategic planning approaches and tactics. However, the CF's objective has always been to identify broad new scientific areas representing trans-NIH challenges and opportunities that can be addressed through finite, short-term, goal-driven programs. NIH Common Fund programs are intended to be:

- *Transformative:* Must have high potential to dramatically affect biomedical and/or behavioral research over the next decade
- *Catalytic:* Must achieve a defined set of high impact goals within a defined period of time
- *Synergistic:* Outcomes must synergistically promote and advance the 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.

Broad-based scientific areas judged to match these criteria would then be further refined into a concept and ultimately a well-defined initiative.

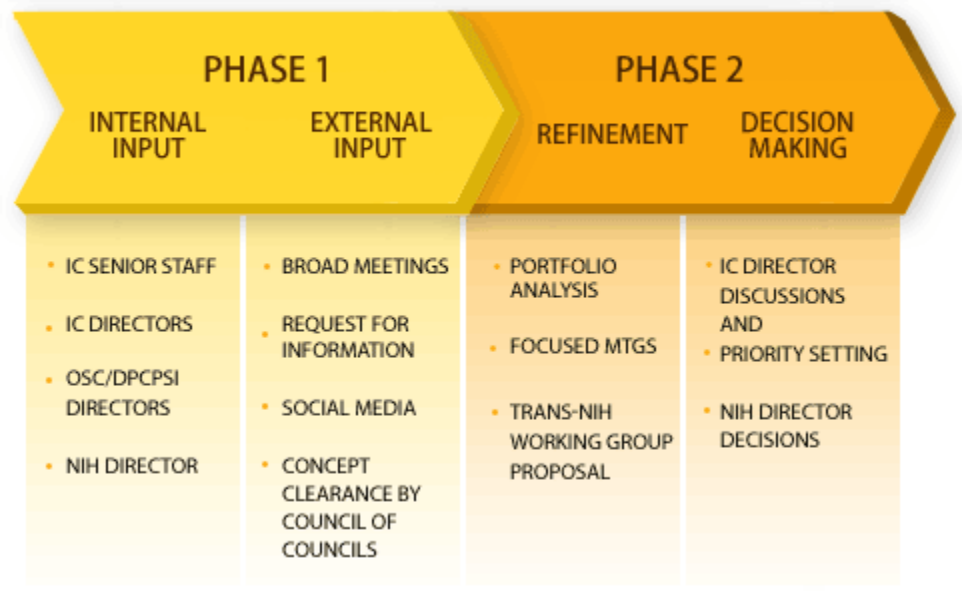
As recounted in the most recent CF Strategic Planning Report (Department of Health and Human Services & National Institutes of Health, 2013), all planning activities are guided by a set of clearly-defined core principles and activities. Early in the process, broad-based input is sought from internal stakeholders, including NIH leadership (NIH staff and IC Directors) representing the perspectives of all ICs to ensure that only ideas with the greatest level of enthusiasm and with the highest potential for broad impact would be further pursued. Input from external scientists capable of representing trans-NIH research interests is sought. Solicitations of new ideas for CF programs are enriched by including representatives from across NIH. Further, the likelihood of selecting the most compelling ideas is facilitated by reviewing many ideas together so that each can be prioritized relative to other concepts.

The decision to move an idea forward to concept clearance, and once cleared, move it ultimately to become a CF program, is guided by findings from an intense, thorough review and analysis of the trans-NIH research portfolio (Portfolio Analysis) to assess the current level of NIH support for all areas of science related to a particular concept. Ideally, the scientific portfolio review is an iterative process that would also help to develop specific initiatives within broad areas to maximize the likelihood that resulting CF programs will make a unique high-impact contribution.

In summary, strategic planning entails identifying broad scientific areas representing trans-NIH challenges and opportunities that are best addressed through finite, short-term, goal-driven programs. Once identified and cleared for further development, CF concepts are then refined into well-defined CF program initiatives. The process is initiated annually and lasts approximately 18 months. Unlike the development of traditional research projects within pre-defined scientific areas at the NIH, strategic planning for a CF project is separated into two phases to allow sufficient time for thoughtful input and informed discussion. This biphasic strategic planning process, illustrated in the Figure, allows a mission to be defined for each project, facilitates knowledge-based decision-making, enables scientific prioritization, promotes a high-likelihood for success, and minimizes the potential for unforeseen obstacles that might lead to failure.

In Phase 1, the broad concepts incorporating scientific needs and opportunities are identified. In Phase 2, successful concepts are refined into specific, well-defined initiatives. The CoC, an external advisory panel to the DPCPSI and NIH Directors, is engaged at the interface between Phase 1 and Phase 2 in an evaluative process called "concept clearance." This process determines which broad ideas receive further consideration as CF programs. Concepts cleared by the CoC are prioritized by the DPCPSI and NIH Directors to identify concepts that should move to Phase 2 planning. Figure 1 describes the framework and major elements of this biphasic process.

Figure 1. Framework for Phases 1 and 2 of CF Strategic Planning



A. PHASE 1 PLANNING

The CFEWG was asked to review, assess, and provide recommendations for changes in four broad areas related to the input and solicitation of ideas, the role of the CoC, and the time available during Phase 1 for strategic planning, including accelerated planning for emergent initiatives.

I. What are the best methods to engage the broader scientific community?

1) Background

Input from the broader scientific community during Phase 1 of strategic planning has been sought from sources both external and internal to the NIH. Between 2002 and 2008, external sources of input included meetings (2002, 2006, 2008) and responses to published Requests for Information (RFIs (2006, 2007-2008, 2008). Since then, the strategic planning process has

matured significantly. Beginning in 2009, strategic planning was initiated through a series of small external meetings to generate broad ideas for new CF programs that focused on the NIH Director's priority research themes. Ideas that emerged from planning activities during prior years were revisited to see if scientific progress had created new opportunities to catalyze research and development in these areas. To create a more diverse spectrum of ideas, a new cycle of strategic planning was initiated in 2010 with a "Big Think" meeting of external and internal experts representing a wide variety of scientific disciplines. These meetings identified three broad themes that encompassed pressing needs, opportunities, and barriers to research discovery and translation: Application of High-Throughput Technologies, Translation of Basic Science, and Utilization of Science to Benefit Health Care Reform. Within these broader themes, two specific project areas emerged from the ideas generated that were selected by NIH Leadership for further development and planning: Single Cell Analysis and Metabolomics.

The following year, in 2011, strategic planning for new ideas amenable to the CF built on lessons from past years and placed even greater emphasis on emerging opportunities. In addition, the biphasic strategic planning process was introduced as a way to facilitate presentation of "big concepts" that would receive thorough review and critical assessment before proceeding with detailed project planning. This new process, which is the one in use currently, was designed to enhance the administrative structure and effectiveness of the overall process. During the first implementation of the new process, identification of new concepts during Phase 1 for CF support came from the efforts of two complementary groups (National Institutes of Health & Department of Health and Human Services, 2011):

1) *NIH Leadership Forum:* This Forum - consisting of the NIH and DPCPSI Directors, IC Directors, and other Office Directors - was asked to consider and think collectively about priorities and needs that affect the entire agency. Although this was not the primary objective of the Forum, any ideas that emerged would inherently be trans-NIH and thus would be appropriate for consideration as a CF project. For example, discussions by Forum participants led to the decision to form an internal task force to consider new models to support the biomedical workforce.

2) *Innovation Brainstorm - Transforming Discovery into Impact:* NIH hosted a meeting of mostly early-career scientists from a wide range of disciplines to identify recent discoveries with a high potential for transformative impact, and to articulate ways in which strategic CF investments could reduce the amount of time for needed to realize this potential. Participants, selected on the basis of their exceptional creativity and innovation, came either from ICs supporting their research or from other awarding institutions.

Also in 2011, the Office of Strategic Coordination or OSC, which administers the CF, conducted an analysis of strategic planning activities that had taken place since 2002 to determine which of the planning activities had been most informative for generating CF

ideas over time. Major findings from this analysis, which included a survey of NIH staff (National Institutes of Health & Department of Health and Human Services, 2011), were used to inform the next round of Phase 1 planning in early 2013 (Department of Health and Human Services & National Institutes of Health, 2013). Four key lessons emerged:

- *Input is needed across a wide range of disciplines, including from individuals outside of biomedical research, and from individuals of various ages and experience levels.*
- *Public meetings are useful for gathering input from external stakeholders, while open-ended RFIs tend to produce extremely broad ideas that may not meet the criteria for CF programs.*
- *Input from the NIH leadership at the conclusion of Phase 1 is critical so that Phase 2 planning focuses on concepts that will be useful to and synergistic with a broad cross-section of IC-supported research.*
- *Portfolio analysis is critical during both Phase 1 and Phase 2 planning, and should be iterative. During Phase 1, analysis helps to prioritize among potential new program areas by determining the level of investment already made in each area. During Phase 2, analysis helps to provide a strategic focus and prevent redundancy with IC investments.*

The 2013 round of strategic planning reflected the full maturation of the process. Strategic planning continued to explore innovative approaches to generate creative and transformative ideas suitable for CF support. As before, these efforts focused on identifying the greatest challenges to research breakthroughs and translation, and the most promising emerging opportunities to catalyze research across a variety of scientific disciplines and disease conditions.

Today, according to the CF Handbook (Office of Strategic Coordination, 2009), the first phase of strategic planning includes the submission of ideas for new CF programs by NIH ICs. Because of their extensive and continuous interactions with external scientists, the ICs are thought to be well positioned to develop ideas reflecting the needs of the broad external scientific community, as well those identified within NIH. Each NIH IC is invited to submit up to two nominations of ideas for concepts relevant not only to the IC-specific mission but across the NIH as a whole. To effectively evaluate the proposed idea, and the potential impact of the program, NIH ICs are asked to address all of the following five questions in their nomination:

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

Concepts emerging from Phase 1 strategic planning activities are reviewed by the CoC during their spring meeting. Concepts that receive less than majority support from the Council are set

aside and removed from further consideration. Concepts that receive majority support are "cleared" for further refinement and development during Phase 2 strategic planning. Ultimately, programs approved by NIH leadership are eligible for CF support beginning the following fiscal year. NIH has expressed the desire to fine-tune its strategic planning process to ensure that new CF programs and activities are responsive to the most pressing needs of the biomedical community.

2) Findings

The CFEWG assessed relevant documents, conducted interviews with NIH staff, and reviewed the 2014 survey responses to assess the approaches and methods to gather input during Phase 1 of strategic planning. Phase 1 planning can best be characterized as "fishing" for ideas to shape into CF programs. Analysis of the "successful" ideas that resulted in new CF programs between 2002 and 2013 revealed that of the 68 ideas considered for CF funding, most were solicited from the ICs (37%) or from meetings with experts in the extramural research community (38%) (see Appendix 6). A smaller proportion of ideas were solicited from other sources (15% from the ACD/NIH Director, 7% from RFIs, and 3% from open public meetings).

Although 37 CF programs were funded during this time, it was not possible to determine objectively which solicitation method was most informative. Interviews with NIH staff suggested that some methods were more likely to generate the kind of informed thinking that gave rise to concepts that eventually became CF programs, while others were less productive. In another analysis of successful and unsuccessful ideas suggested between 2002 and 2013 (see Appendix 7), ideas generated in meetings either with invited "thought leaders" or in open community meetings resulted in "consensus" ideas (e.g., Citizen Science, Deorphanizing the Druggable Genome, Glycomics, Mechanobiology). Group discussions tended to refine concepts submitted at the beginning of the meeting by individual attendees. These individual ideas (e.g., A US National Cohort for Health, Genomics, and the Environment, and Metabolomics for Clinical Medicine) were captured in meetings with thought leaders, not in meetings that were open to the community.

Irrespective of the methods used to solicit and generate ideas for CF programs, we found that consistency, clarity, and transparency in the decision-making and prioritization processes used to develop an idea into a CF concept suitable for CoC clearance were important and appreciated by all involved. Interviewees and survey respondents noted recent efforts to improve the consistency and openness of the processes. We heard encouragement for NIH to continue these efforts, especially with regard to enhancing communication and interactions between OSC staff and ICs. An overwhelming majority of IC Directors and staff interviewed felt that the missions of the various ICs benefit from participating in the CF; that CF investment is an effective use of NIH resources; and that the CF has increased the likelihood of collaborative and high-impact trans-NIH programs and activities. Despite the increased workload associated with participating in the CF, we found that there has been a positive shift in attitude about the CF since 2005 (ORC Macro, 2005).

A. Process the ICs Use to Submit Ideas for Common Fund Programs

As part of the annual solicitation process, OSC sends a one-page template to all ICs to use for submission of ideas for new CF concepts. Individual NIH ICs have their own processes for responding to these requests. The CFEWG interviewed NIH IC Directors and staff to understand if these internal processes to respond to OSC's solicitation could provide insights on how to better engage and solicit ideas from the broader scientific community. While there were a variety of informative comments, a common theme was that solicitation requests were regularly shared with staff at varying levels to gather ideas. This could be accomplished through meetings with senior staff to promote discussions among division directors and colleagues about potential ideas, with the most promising being further developed and submitted. Electronic communications (e.g., emails) used to solicit ideas from staff, internal leadership teams, or division leaders are then followed by in-person meetings to discuss, prioritize, and in some cases vote on concepts to submit back to OSC.

Irrespective of the internal processes employed, the extent to which ideas are ultimately submitted back to OSC varies considerably among ICs. Some IC Directors expressed enthusiasm and noted that their IC actively participates in efforts to seek external input on ideas, and regularly submits ideas for consideration by the CF. Small to mid-size ICs were particularly active during the early strategic planning process. However, it was also noted that subsequent steps in the process, including the final Phase 2 decision on selection of a proposal to become a CF program, were sometimes unclear or inconsistent.

In some cases, the nature of the solicitation determines the process an IC uses to submit ideas for CF support. For example, some requests for input might be better targeted at staff, while others should be forwarded to external IC Council members. Staff at one IC might approach their counterparts in another IC to develop an idea, and then build a coalition to develop and submit a proposal for consideration. The ideas gathered during these discussions are then presented to the IC Directors and executive staff who discuss the initiatives, some of which lead to not only CF concepts but also to initiatives that an IC might take on internally.

In some years (e.g., 2006), senior program staff would filter incoming concepts and develop a priority-weighted list of concepts that was then sent to IC Directors for consideration. The lack of an ideal mechanism to manage the challenge of filtering so many ideas has led OSC staff away from gathering a lot of ideas (doing a "*big ask*"), and toward a more strategic approach in asking for ideas. In other years, there were no external efforts to gather ideas. For example, in 2007-2008, 16 ideas gathered in previous years were revisited, resulting in two being chosen as new CF programs (i.e., GTEx and NIH Director's Transformative Research Awards or TRA). In 2009-2010, the director reviewed ideas posited the previous year and held meetings to develop proposals. From this, 11 new CF programs emerged from 13 ideas.

Occasionally, ideas submitted to NIH leadership and IC Directors are too vague and need to be improved considerably before further consideration. At other times, repeated submission of

ideas, especially those that have already become CF projects, could have been avoided had the ICs been more thoroughly informed about currently funded projects.

The general sentiment was that the ICs play a very important role in the gathering of ideas for CF concepts. Some staff felt that more time should be spent advertising the CF internally to the ICs to increase awareness of and energize enthusiasm for the CF.

These interview findings were consistent with survey responses. A plurality of survey participants were satisfied with the current process for soliciting ideas from ICs (agree: 41%, neutral: 35%, disagree: 23%). An even higher proportion of respondents were satisfied with the mechanism OSC uses to solicit ideas from the ICs (agree: 55%, neutral: 34%, disagree: 11%). Several respondents commented positively about collaborating with other ICs on CF programs. A large majority of survey respondents felt that their involvement in the CF made good use of their skills and abilities (agree: 84%, neutral: 10%, disagree: 6%). These results reflected an improvement in satisfaction with involvement in the CF compared to responses to the 2005 survey (agree: 49%, neutral: 33%, disagree: 17%).

B. Methods to engage the broader scientific community

Analysis of CF strategic planning activities from 2002-2013 (see Appendix 8) and the 2011 CF Strategic Planning Report (National Institutes of Health & Department of Health and Human Services, 2011) shows that the strategic planning process has evolved over the years to become a broad outreach effort seeking a diversity of input. Outreach efforts included invited expert meetings, open meetings, and (occasionally) electronic solicitations. In interviews, IC Directors and staff indicated that over the last several years, the various methods for generating and soliciting CF ideas have helped them to understand what methods work better than others.

Early on, external input was gathered electronically, such as through publication of an RFI. Ideas generated through RFIs (e.g., A Resource of Affinity Reagents for Analysis of the Human Proteome, Infrastructure for Very Large Data Repositories and Data Mining) have been found to be suitable for CF support. However, IC Directors and OSC staff agree that for the most part RFIs have not been a sufficiently effective mechanism to solicit and generate relevant CF concepts. The unique criteria of a CF program requires an interactive discussion. In fact, the number of comments in response to RFIs could be overwhelming, creating a large workload for staff. Because responses to an RFI were often too broad and did not fit the explicit criteria of the CF, the general feeling expressed by several interviewees was that solicitation through publication of an RFI was not effective for Phase 1 of strategic planning. On the other hand, RFIs could be more informative and useful for Phase 2 of strategic planning.

Expert meetings are one alternative and productive approach for generating useful ideas. At expert meetings, people with a broad diversity of expertise (from basic through clinical) are invited, with the expectation that common themes and concepts will emerge. Participants are asked to consider today's challenges in biomedical research. Very broad challenges are then

shaped into more concrete ideas as the meeting progresses. The 2013 CF Strategic Planning Report (Department of Health and Human Services & National Institutes of Health, 2013) confirmed that having more such meetings leads to more ideas submitted for consideration as a CF program (e.g., a doubling between 2011 and 2013). Ideas tend to be more innovative when generated by a diverse cross-section of meeting participants that includes young and mid-level researchers. It was noted that though external meetings with younger scientists were lively, the scientists' views could be narrow or uninformed. In these cases, their contributions to the development of effective and workable ideas was less relative to those from more seasoned experts and established investigators who were better at "thinking big." However, some staff felt that meetings held with young investigators could stimulate new and exciting ideas for the future.

The NIH has also held two regional meetings (in 2011, in Chicago and San Francisco) that were open to the public. The community was informed about participating in these open meetings through emails to grantees, advertisements on the NIH website, and social media. Staff suggested that despite this outreach effort, it was difficult to thoroughly canvass the entire scientific community, and oftentimes only a small subset could be reached. Nonetheless, meetings were attended by people from diverse areas of science. Discussions at these meetings allowed people to consider the challenges facing science, and these challenges were considered appropriate topics for the CF. However, these open meetings were less likely to lead to actionable ideas compared to invitation-only meetings of experts.

The consensus view is that the vast majority of CF concepts appear to arise from expert meetings and internally from ICs, while fewer arise from open public meetings and RFIs. However, although expert meetings were more productive in generating more useful ideas and meaningful outcomes than public meetings, the public meetings were nonetheless rigorous and informative. OSC staff noted that holding regional and local meetings to solicit ideas from experts in the external scientific community have been quite successful. Local meetings were considered valuable for learning and "filtering" ideas in advance of larger meetings with outside experts, although interviewees noted that ideas were not substantively different between either type of meeting. It was suggested that scheduling external meetings in association with large, national scientific congresses could increase the pool of experts from which to invite meeting participants.

The variability in perceived value of open versus invitation-only meetings probably has contributed to the mixed feelings expressed by some IC Directors regarding the value of CF ideas solicited from outside the NIH. One remarked that ideas received from the external community were of limited value compared to ideas received from within the ICs.

Comments likely reflect a need for even greater emphasis on clarity, transparency, and feedback in the planning and decision-making process for CF projects. Broader appreciation and "buy-in" to the significant financial investment in the CF can increase if there is emphasis on awareness

about the CF and on efforts to inform the scientific community, including the NIH, of the scientific value and accomplishments of the CF program.

CF programs that arise from the Advisory Committee to the Director (ACD) are perceived to be derived solely by the NIH Director, and thus might be seen as too "top down." It should be made clear to all NIH staff that ACD Working Groups typically conduct extensive outreach to the research community as they develop recommendations. Programs that emerge from the ACD as well as the external scientific community can be more difficult to launch because they can lack the initial buy-in from IC Directors and the "grass-roots" WG environment.

We found that approaches for soliciting new ideas that are appropriate and relevant to the CF could be improved and refined. Although different approaches have been successful in soliciting ideas from one year to another, there seems to be a need for more creative ways and processes to generate innovative ideas that align with the CF mission. A minority opinion, expressed by some IC Directors, was that there simply are not as many potentially transformative concepts now compared to when the CF was first launched. This could be explained in at least two ways. First, establishing a support mechanism for transformative, trans-NIH programs that had no other funding outlet until the advent of the CF released a pent-up backlog of ideas that became CF projects. Alternatively, greater attention today to the specific CF criteria limits the number of relevant ideas that best "fit" the CF mission. OSC staff reported that in one year, some ideas submitted by ICs duplicated those from a previous year. These observations suggest a need to actively engage more ICs and be more creative in identifying CF-relevant concepts.

Increasing outreach about the CF for the external research community is a valuable exercise. There is a widespread misconception that funding for the CF is derived from ICs' budgets, and that this reduces funding from those ICs for other investments (e.g., researcher-initiated projects). To ensure continued and growing enthusiasm for the CF and CF investments, it is important for the broader research community to understand the goal and purpose of the CF, and to perceive that its budget is funded from within the OD. For example, comments received suggested that new ideas could emerge from non-CF-related trans-NIH discussions if funds were available to host workshops and symposia that engage the broader research community, likening this approach to a grass-roots development effort.

Early ideas for concepts that ultimately became CF programs were highly varied and diverse. Some, such as The Human Microbiome Project and The Undiagnosed Diseases Program, were highly innovative and disruptive. Others, such as Illuminating the Druggable Genome, may not be recognized as visionary when first proposed, but evolve through planning. Because paradigm-shifting ideas are rare, supporting only ideas that have majority buy-in may favor ideas that are by nature less disruptive and may be less innovative. The risk is then that CF support will only result in incremental progress and will miss opportunities to invest in significant ideas with the potential to make visionary scientific advances.

C. Process for recommending experts to participate in CF strategic planning

IC Directors rely on personal knowledge of individuals to make recommendations for external experts to participate in CF strategic planning meetings. These individuals are often leaders within the ICs' grantee communities and councils. The characteristics of a "thought leader" include the ability to think broadly and in an interdisciplinary way about topics that effect biomedical research, as opposed to an individual with "content expertise." Additional factors that are considered in the selection of thought leaders for these meetings include geographic location, demographics, scientific maturity (for both established and early-stage investigators), technological competence, among others. Analysis of CF reports attest to the value of inviting people from a range of career stages to participate in CF strategic planning meetings (from post-docs to full professors) as long as expectations are managed.

A minority view noted that some IC Directors felt that they did not have the opportunity to provide adequate input into the process; they did not know who populates the final list of experts or understand how they are selected for participation in planning meetings. We note that such comments usually reflect the need to provide greater clarity, transparency, and feedback about the planning process.

II. Do the concepts, as currently written at the end of Phase 1, allow effective review by the CoC? Should the format and content of the concepts be adjusted? Should DPCPSI more stringently filter concepts that are not clearly articulated and ask the CoC to review only those concepts for which there is enthusiasm?

1) Background

As an external advisory body to the Office of Strategic Coordination (OSC) in the OD, the CoC provides input to the NIH on ideas (or concepts) with broad scientific impact that extends beyond the research community served by any one Institute or Center. The CoC was established in 2006 and began providing input on CF concepts in 2008. Between 2008 and 2012, CoC provided input on CF concepts during Phase 2 planning. More recently, starting in 2012, CoC served as a sort of gatekeeper for ideas that were generated during Phase 1 strategic planning and developed into concepts ready for transition to possible projects during Phase 2 strategic planning (see Appendix 8). At this transition step, CoC conducts a "concept clearance" that deems ideas at the end of Phase 1 as either not sufficiently ready and mature, or worthy of further development, investigation, and maturation prior to entering Phase 2. The latter are chosen on the basis of whether the idea or concept fulfills the fundamental criteria of a CF project and thus has high potential for receiving funding support as a CF project.

2) Findings

The objective for CoC is to get a sense of what a good vision for the concept might encompass. Currently, at this stage, Phase 1 concepts are framed with little analysis. Instead, they articulate a compelling need emerging from either a Phase 1 planning meeting or the IC Directors. A more in-depth analysis, requiring significantly more thought and action, occurs during Phase 2.

At present, CoC is provided with brief reports on CF concepts that have completed Phase 1 planning (see Appendix 9). These reports focus on answers to five major questions:

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

The comprehensiveness of these reports and the breadth and depth of responses to the questions varies between CF concepts. The responses are useful for making an informed decision. However, additional information would be helpful - for example, how does the proposed concept fulfill the CF criteria, and what are the potential costs if the proposed concept advance to a CF program? While preliminary information about cost could potentially save the time and effort of discussing a concept that is too expensive to implement, concepts at this early stage of development might be too amorphous to have accurate cost estimates.

OSC staff welcome input and advice from CoC on concepts. Such comments, especially on concepts that are "cleared" by CoC, can help inform Phase 2 planning. However, it appears that comments made by CoC members on individual concepts often do not reflect the overall vote to "clear" or "not clear" the concept. CoC appears reluctant to clear a concept that is amorphous because, depending on how it develops during Phase 2, it may or may not be transformative. However, CoC can provide guidance on how a concept could evolve to make a transformative outcome more likely. To do so, CoC would need more time than is currently afforded during the brief presentation at the CoC meeting to consider a concept. For that reason, either fewer concepts should be scheduled for discussion at CoC meetings, or more time afforded for discussion of all relevant concepts.

Decisions to filter or prioritize concepts to reduce the number presented for consideration by CoC should be carefully considered with all stakeholders. Presumably, any ideas that have developed over nine months into a concept should already have met the fundamental criteria for what a CF program is intended to be (unique, transformative, synergistic, catalytic, and cross-cutting). In principle, all of those concepts should be presented unless all stakeholders (relevant OSC staff, IC Directors and staff, and NIH leadership) come to agreement otherwise.

A Planning and Evaluation Team consisting of staff from OSC, provides first-level analysis of ideas submitted for CF consideration. DPCPSI leadership decides which ideas are clearly inappropriate for CF funding, and these are not considered further. An alternative decision-making process by which OSC and DPCPSI Directors confer with IC Directors would enhance and improve transparency and understanding of nuances that make one idea more appropriate than another for CF consideration.

The absence of a designated process understood by all stakeholders can be problematic and create challenges for OSC staff. Further, potentially innovative concepts might not be considered. For example, an otherwise promising concept that is not quite ready for presentation to CoC might never be considered again. Other concepts could benefit from additional information or clarification that would increase the likelihood of a more favorable judgment by CoC and subsequent transition into Phase 2 strategic planning. Therefore, if the decision-making process remains at the discretion of the OSC and DPCPSI Directors, then clearly define and articulate the criteria for the decision. Alternatively, consider including IC Directors into the decision-making process. Well-described and clear criteria in a process that is more inclusive will not only help ICs and others better understand the process, but will also help guide the thoughtful generation of ideas that are more relevant to the CF.

Survey respondents were evenly split as to their satisfaction with the prioritization process for selecting ideas for further development in Phase 2 (agree: 30%, neutral: 39%, disagree: 31%). Most respondents were unsatisfied with the level of feedback they received about how CoC concepts were either cleared or not approved for moving forward (agree: 30%, neutral: 28%, disagree: 42%). We interpret these results as a need for enhancements and modifications to current practices - specifically regular communication and reliable feedback.

III. Is nine months for Phase 1 planning an appropriate time frame?

1) Background

Phase 1 of the strategic planning process is approximately a nine-month process that begins by identifying broad scientific needs and opportunities that are not currently being met by ICs, are likely to fulfill CF criteria, *and* have the potential to meet the goals and milestones that characterize a CF project (Department of Health and Human Services & National Institutes of Health, 2013). This process entails gathering external and internal input for six months (from January to May) followed by "vetting" and "filtering" for another three months (from May to July; Office of Strategic Coordination, 2009). During the first six months, input is sought from both internal sources (informal and formal meetings, senior NIH staff, IC Directors) and external sources (meetings with external scientific experts and stakeholders, RFIs from the public, social media, and so on). During the ensuing three months after the spring CoC meeting, cleared concepts are further developed in preparation for discussion and prioritization by IC Directors and NIH leadership. The NIH Director then makes the final decision as to which CF project ideas can advance into Phase 2 and be developed into CF program proposals.

2) Findings

Interviews with IC Directors and staff and survey respondents provided different perspectives regarding the time afforded to Phase 1 strategic planning. The different approaches to strategic planning over the last several years have extended the time available for Phase I planning. Considering the 10-year history of the CF, many interviewees indicated that IC program staff are already attuned to thinking ahead and long-term planning within their respective ICs, so that generating ideas for CF projects becomes a compilation of ideas that does not require an extensive time commitment. Further, a near-majority of survey respondents felt that the strategic planning process allowed sufficient time to develop initiatives (agree: 47%, neutral: 27%, disagree: 26%). These responses represent a positive shift in attitudes from 2005, when a higher percentage of respondents felt that not enough time was allotted for strategic planning (agree: 38%, neutral: 18%, disagree: 44%). It should be noted that in 2005 the strategic planning process was uniphasic, not biphasic, as it is today. In addition, more respondents than not were satisfied with the pace of and time provided for the strategic planning process (satisfied: 40%, neutral: 35%, dissatisfied: 25%). These results also represent an improvement in opinion since 2005, when a plurality of respondents to the survey were dissatisfied with the pace and time provided for strategic planning (satisfied: 36%, neutral: 21%, dissatisfied: 43%).

Conversely, some interviewees and survey respondents felt that the existing formalized process could be time-intensive, cumbersome, and hurried. Some felt that six months was not sufficient time for ICs to develop collaborative CF proposals. Still others had mixed opinions, suggesting that while the overall time frame was workable, the process itself was slow and overly bureaucratic. Others even felt the process was too slow for well-developed concepts, and could be streamlined. Harder to decipher were comments by some staff that while the timeline was appropriate on paper, they were often not able to stick to it for "reasons beyond their control."

These comments generated discussions within the CFEWG about facilitating more flexibility during Phase 1 planning to enable ideas to be vetted in a more timely fashion as they arise. Under the current administrative structure, all concepts are collected at once. This allows for prioritization, but it means that only fully developed concepts compete, and some great concepts may not progress. Therefore, increasing flexibility in the process could allow more time for ideas to mature and develop into CF relevant concepts, but would eliminate the ability to prioritize among a group of concepts presented simultaneously.

Essentially, the immediate cost of more flexibility is less efficiency. After Phase 1, NIH leadership considers available resources, such as funding and staff availability, when prioritizing CoC-cleared concepts for Phase 2 implementation. Because of limited availability of funds to start a program, OSC uses this process to choose which of several concepts to implement. Not having all concepts ready for a side-by-side comparison at the same time on the calendar makes this process unworkable. Instead, under a flexible Phase 1 approach, individual concepts would be considered for Phase 2 planning on a "one at a time" basis. Consideration of concepts as they

arise would become more time-consuming process than it is at present, and less efficient. Further, the absence of a prioritizing process could reduce the transformational mission of the CF program. Because the purpose of the CF is to provide solutions to challenges that are not currently being met, any and all mechanisms that can facilitate this goal should be considered, as long as they are administratively and financially reasonable and comply with the characteristics and mission of the CF program.

One way to enhance flexibility and to address concerns about the time constraints of Phase 1 planning could be to consider a shorter version of CF investment, such as one- or two-year pilot projects. A pilot project may need more work to develop; however, a fast-track pilot process could shed light on whether a concept has the potential for becoming a CF program, and can gauge staff enthusiasm for the idea. This process may give more flexibility on how to proceed during Phase 2.

IV. Should an alternate process be developed for rapid planning for urgent needs?

1) Background

Rapidly emerging challenges and opportunities are addressed in a number of ways at the NIH, depending on the funds required and the complexity of the problem:

- Individual grantees may use their awards to go in new directions, in discussions with the grant's Program Officer as necessary. This is a critical feature of the Pioneer and New Innovator awards, but is also common within the context of R01s and other discovery-oriented awards.
- Supplements may be made to grantees to provide necessary funds, as long as the new work does not represent a change in scope from the original award. Supplements are widely used within the CF to take advantage of new opportunities. An example is the expansion of the KOMP^2 program to include developmental phenotyping. The high rate of embryonic lethality (30%) of the mutants provided a chance to understand the contribution of these genes to early development, and the CF was able to take advantage of this opportunity.
- Intramural investigators have the flexibility to change their research plans as needed. ICs may increase an individual investigator's funds, as resources permit, to support critical research areas.

"Rapid response" in these situations assumes implementation of an action plan within days, weeks, or a few months. This compares to the nine months or more required for review and award of an extramural grant application. Each rapid response mechanism has been used to respond to specific needs of previously established and ongoing CF programs. In none of the *existing* CF programs has the rapid response mechanism been used to address an emergency.

In one instance thus far, the emergent opportunity and immediate needs of an unforeseen event catalyzed the establishment, funding, and implementation of an entirely *new* CF program, the Gulf Long Term Follow-up (GuLF) Study, as a rapid response to an emergency concept (see Appendix 10). The GuLF Study was prompted by the April 20, 2010 explosion of the Deepwater Horizon oil rig in the Gulf of Mexico. Concern over the safety of oil spill workers and volunteers led to an effort by the National Institute of Environmental Health Sciences (NIEHS) to establish a longitudinal study of people exposed to oil and dispersants. Within two months of the incident, on June 15, 2010, the NIH Director announced an investment of $10 million from the CF to support the initial stages of NIEHS launch of this research. Recognition that the exposure could potentially affect all organ systems, and that understanding the impact of the spill had trans-NIH interest, warranted CF investment. Detailed plans for the project were developed by the NIEHS principal investigator (PI) through conversations with the OD/DPCPSI, extensive community outreach activities, and discussions with other federal agencies.

2) <u>Findings</u>

While emergent needs within existing program areas are considered by the relevant WG, there is no defined process for review of proposals for *new* emergency concepts, and there appears to be no clear definition about what constitutes a rapid response to an emergency concept, or how an emergency concept can be distinguished from other high-priority concepts. Further, a process for determining whether an emergency concept is relevant to the CF mission does not exist. The only CF rapid response to an emergency concept, the GuLF program, was initiated outside the regular strategic planning process and was driven from the top down, in contrast to the bottom-up model discussed above. Certainly, the nature of the disaster and its potential impact on millions of people was an emergency, but the rationale for how the need to monitor the health consequences was relevant to the CF mission is unclear.

Nonetheless, what this situation suggests is that the design of the "regular" 18-month CF strategic planning process is not compatible for emergency situations that might represent trans-NIH interests. The fact that there has been only one CF program representing a rapid response to an emergency concept implies either that there have been no other emergency situations that warrant CF investment, or that other emergency situations have arisen but have not been presented or considered appropriate for CF investment. IC Directors recently questioned whether the CF needs a mechanism outside its regular strategic planning processes to initiate a rapid response to an emergent challenge or opportunity. OSC staff state that they can work within current processes, and that the ability to rapidly respond to emergencies does not require a separate mechanism.

B. PHASE 2 PLANNING

V. Do Phase 2 processes result in clearly articulated goals and expected milestones?

1) Background

Phase 2 focuses on processes for refining and making decisions about concepts that were advanced from Phase 1. This phase entails conducting portfolio analyses, holding focused meetings, and developing a trans-NIH working group proposal. The NIH Director makes the final decision at the end of Phase 2. The portfolio analysis helps to determine the extent to which the NIH may already have invested in the topic area. The outcome of the analysis may alter the focus of the concept and affect the final goals of the new program. For example, the portfolio analysis for the Epigenomics program identified the need for more investment in this area. Very few genome-wide analyses were being conducted at the time the portfolio was considered, and the capacity to do these types of analyses was limited.

In 2006, a portfolio analysis was conducted by NIH staff. There is currently an office within DPCPSI that has an active outreach and training program to teach staff across the NIH how to do portfolio analyses.

The CFEWG reviewed the extent to which goals and milestones changed during the evolution from a concept to a program. The CFEWG reviewed three programs that evolved in different ways: Extracellular RNA Communication (see Appendix 11), Epigenomics (see Appendix 12), and Single Cell Analysis (see Appendix 13). Of these, the Extracellular RNA Communication program was an example of a concept that changed considerably from inception to implementation. Consequently, the focus and goals of the program changed as well.

For example, the goal of the original Phase 2 program proposal was to develop a knowledge base, tools, and resources to exploit the understanding and use of extracellular vesicles (EV) in human health and disease. However, after approval as a CF program, the specific goals of the program evolved to focus on development of tools/technologies/methods for isolation and analysis of various classes of exRNAs rather than extracellular vesicles. The goals for the individual initiatives were also clarified: establishing a central data repository for the research community, establishing profiles of *human* exRNAs from multiple tissues and body fluids, and "support[ing] projects that demonstrate possible utility of exRNAs as biomarkers or therapeutic delivery vehicles." Subsequently, the WG submitted detailed plans to the OSC, describing overall program goals of establishing fundamental biological principles of exRNA secretion, delivery, and impact on recipient cells; describing exRNAs in human biofluids and the extent to which exRNAs from non-human cells were present; and testing the clinical utilities of exRNAs. This brief history illustrates how the goals and milestones can change with the evolution of the program. They reflect additional considerations, pruning, and refinement of the program in the

course of discussion, so that the program became more pragmatic with respect to results and achievable goals.

2) Findings

The CFEWG examined relevant documents, conducted interviews with NIH staff, and reviewed the NIH-wide survey responses to assess the clarity of goals and milestones developed for Phase 2 CF processes. From an extensive review of three programs and discussions with OSC staff, the CFEWG concluded that the clarity of goals for a particular program was often related to the specificity of that program and the quality of the portfolio analysis. If a program was more specific and focused initially, the goals were more clearly articulated. However, there were concerns expressed about having programs so narrowly focused that they might not address all the relevant scientific questions.

The interviews with NIH Directors, OSC staff, and various WG members did not specifically cover the clarity of program goals that would flow from Phase 2 processes. However, interviews with OSC staff did cover portfolio analysis. OSC staff noted that the quality of the portfolio analyses varied from program to program. One OSC staff member added that when a program did not have clearly articulated goals, the program struggled and could take a few years to get back on track.

The NIH-wide survey indicated that participants generally felt that the strategic planning process results in clear goals. When asked to state their agreement with the statement "...*The process results in clearly articulated goals and milestones for CF programs*," most respondents agreed (agree: 45%, neutral: 31%, disagree: 24%).

Survey participants were also asked their opinions of the strategic planning process in general. A majority of respondents felt that the strategic planning process is guided by a clear set of goals (agree: 56%, neutral: 24%, disagree: 20%). In support of this assessment, an overwhelming majority of respondents felt that it was critical to conduct portfolio analyses during the program planning phase (agree: 90%, neutral: 8%, disagree: 2%). Though respondents felt strongly that portfolio analysis was crucial, narrative comments from survey participants indicated varying opinions of how *well* it is done. One respondent noted that the portfolio analyses being conducted were inadequate to assess needs, innovations, and rapid advances in research.

During interviews with NIH staff and IC Directors, nine participants commented on the need for clear goals and milestones in CF programs. One participant noted that the goals and timelines should be clear and realistic. Another said that clear deliverables should be required in developing concepts. A third participant felt that goals should be clearly communicated to WGs when they are formed. An important point raised by another participant was that CF goals should rise above the needs of specific ICs. An interviewee said that it should be clear how evaluations of programs are implemented, and another felt that measurable milestones and benchmarks should be established at the inception of the proposal. Considering that OSC also recognizes and

agrees on the importance of establishing goals and milestones for CF programs, these comments highlight the need to enhance clarity in communication and regular reminders and feedback to all stakeholders.

VI. Is 9 months an appropriate timeframe for Phase 2 planning?

1) Background

Phase 2 of the strategic planning process includes refinement of and some decisions about concepts that advance from Phase 1. The idea-refinement portion of the process includes the WG conducting the portfolio analysis to determine the extent to which the topic has already been or is being addressed by NIH or other entities; gathering internal and external input to assess needs, gaps, and opportunities; and creating the proposal itself. This planning process of idea refinement proceeds for eight months - from August through March - and the proposal is presented to the NIH Director in April/May. Detailed implementation plans are drafted at the end of May (Office of Strategic Coordination, 2009).

2) Findings

The NIH-wide survey asked respondents specifically about the time allocated to two aspects of planning in Phase 2: conducting the portfolio analysis, and gathering input from the scientific community for program ideas. Respondents differed as to whether the time allocated for portfolio analysis was adequate. A plurality of participants felt that the process provided adequate time for portfolio analysis (agree: 43%, neutral: 34%, disagree: 23%).

When asked specifically about the time provided to solicit input for refining broad program ideas, a majority of respondents either agreed or were neutral on whether they were satisfied with the time allotted (agree: 42%, neutral: 32%, disagree: 26%).

When asked about their level of satisfaction with the time provided to refine broad program ideas into specific initiatives, most respondents were satisfied (satisfied: 50%, neutral: 28%, dissatisfied: 22%).

Perhaps reflecting a mixed message regarding time available, survey respondents gave mixed comments on the timeframe for strategic planning. Eight respondents felt that various parts of the strategic planning process did not allow enough time, with one specifically noting that too many activities need to occur within the time allowed. Six respondents commented that the strategic planning process takes too long, with one specifically noting that the process *"can be too slow for well-developed concepts."* Again, the institutes from which respondents came might have influenced whether there was sufficient help for them to meet deadlines, which may have affected their responses and caused some of the mixed responses.

VII. Do IC Directors and the CoC have appropriate levels of input to guide the development of Phase 2 proposals?

1) Background

Concepts cleared and advanced from Phase 1 are refined in Phase 2. Trans-NIH WGs are formed for each concept during the August/September timeframe, and two or three IC Directors nominate themselves or their senior staff as Co-Chairs or Coordinators of the WG. IC Directors nominate staff to participate as members or initiative leaders.

Working Groups refine the concepts during the October-March timeframe. This refinement includes conducting a *portfolio analysis* along with other meetings and workshops as necessary. IC Directors and the CoC are updated on the program around the halfway point (~January) and provide guidance to the WGs.

Proposals are completed and reviewed by OSC during March, and then are presented to the NIH Director and the IC Directors the following month. WGs follow up on questions from the Directors and make changes discussed at the Directors meeting, following which a final decision is made to start or not start the program by the NIH Director (see Appendix 14).

2) Findings

Five of 11 IC Directors who were interviewed felt that they did not have adequate input into the decision-making process. One noted, *"Once the submissions of the proposals are made, there's very little understanding of what's happening next and very little opportunity for feedback and participation in the subsequent steps of decision-making."* Another IC Director simply stated that there was no opportunity to provide input into the process. Five IC Directors noted that they would like to provide input and receive communication on decisions. While there are established processes for providing input, there is a need to improve communication and to provide regular feedback to ICs on the progress and development of CF proposals.

In the survey, respondents were asked about their level of satisfaction with the CoC's role in the process of approving ideas to become programs. Interestingly, a plurality of respondents held no opinion about their satisfaction with the CoC's role in concept clearance, although few disagreed (satisfied: 37%, neutral: 50%, dissatisfied: 13%).

IC Directors were asked specifically whether they were satisfied with *their* level of input into the process for selecting new CF programs. Most Directors felt that the process did not allow adequate input (agree: 33%, neutral: 22%, disagree: 44%). Again, disparate views were reflected in the leadership as well as the staff.

C. PHASE 1/PHASE 2

VIII. What should the process be for planning intramural-only programs?

1) Background

A document that describes the planning of Intramural Research Programs (IRP) was reviewed (see Appendix 15). Most CF award solicitations are open to applicants from all organizations, including the NIH IRP, with the goal of supporting the best science regardless of where the research is conducted. There are occasions when the IRP has been determined to be uniquely positioned to address key roadblocks in biomedical research as part of the CF. In these cases, funds are allocated to the IRP without competition with extramural applicants and are thus considered IRP-only programs or initiatives (an initiative is one component of a multi-component program).

From fiscal years 2004-2006, the NIH Roadmap programs were supported by combined funds from each of the ICs, with each IC providing 1% of its appropriation to the pool. Since these funds "came off the top," i.e., before funds were allocated to intramural or extramural programs, both intramural and extramural investigators were intended to benefit from the programs and to be eligible to receive funds. During the planning stages for the initial set of Roadmap programs, initiatives were designed exclusively for either intramural or extramural; competition between the two did not occur. However, as additional programs were planned in 2006, NIH leadership questioned whether programs or initiatives should be developed exclusively for one or the other.

In 2007, a group of IC Directors who advise the NIH Director on trans-NIH operational activities (the NIH Steering Committee) provided guidelines that would determine how the NIH IRP should be involved in CF programs. Recognizing that certain strategic objectives might best be met by the IRP, while others might be suitable only for investigators in the Extramural Research Program (ERP), the Steering Committee determined that the IRP-ERP contribution to each program or initiative should be considered on a case-by-case basis. The expectation was that goals might generally be achieved by investigators in either the IRP or the ERP and that awardees should therefore be selected via competition with peer review; clear justifications for IRP-only or ERP-only programs or initiatives would be required.

Criteria established for designating Intramural-only programs require that the goals of the initiative:

- Must be implemented rapidly. (See Appendix 10 for a separate discussion of this type of program.)
- Benefit from access to the unique patient populations or resources that are available in the NIH Clinical Center or other facilities within the IRP.

- Focus on developing a resource that is "inherently governmental" because it needs to be in the public domain, and, if successful, will require stable, ongoing support.

Planning for IRP-only programs and initiatives has been variable, as described below for five representative initiatives:

- **PubChem (2004):** The Molecular Libraries and Imaging program was designed to provide the capability and data management resources for small molecule assay development and screening, chemical library development, and imaging probe development to intramural and extramural investigators.
- **Imaging Probe Development Center (2004):** A second Molecular Libraries component, IPDC, was created to address the dearth of probes available for molecular imaging. A core facility was established to provide imaging probes not available through a commercial supplier and to generate novel imaging probes (e.g., optical, PET, SPECT, and MRI).
- **Re-Engineering the Clinical Research Enterprise – Clinical Research Training Program (CRTP):** The CRTP began as one of a series of complementary initiatives within the NIH Roadmap that would facilitate clinical research and that emphasized training clinician scientists.
- **Epigenomics – Data Management (2007):** The CF Epigenomics Data Management Center was created specifically to provide public access to the data generated by the Epigenomics Program along with data from other National Center for Biotechnology Information (NCBI) resources, NIH ICs, and the international community.
- **NIH Center for Regenerative Medicine (NIH CRM, 2010):** Recognizing the unique clinical and translational resources that the IRP could bring to the development of cell therapies using induced pluripotent stem cells (iPSCs), the NIH CRM was developed within the IRP to identify and overcome the translational challenges of iPSC therapies.

2) Findings

The process for launching any CF program is first to establish a goal and then determine the best way to achieve it. For example, the goal for the NIH CRM was to translate the potential of iPSCs cells into autologous cell-based therapies. The IRP was determined to be the appropriate place to accomplish the goal because of the unique strengths of the NIH Clinical Center, including access to rare patient populations and unique clinical care capabilities.

Unlike awards to extramurally-funded programs that are reviewed by advisory councils, awards for IRP programs are not similarly reviewed. Further, the development of concepts for IRP initiatives do not receive clearance by advisory Councils. These NIH-wide policies are true for CF IRP programs and initiatives as well, so CF IRP-only initiatives are not reviewed or discussed by the CoC.

The GuLF Program, discussed earlier as an emergency concept, is also an example of an intramural program requiring rapid implementation as a response to an emergency that required

an immediate follow-up with the affected population. Launching as an IRP was the fastest means of establishing the GuLF Program. Funds were provided to NIEHS quickly to launch the project as soon as possible. Supporting this program through the IRP also facilitated extensive interagency coordination, which was a requirement for the program as a governmental collaborative endeavor to assess the public health impact of the oil spill.

The process for rapidly securing extramural awards is through a supplement to an existing award. The limitation is that the work to be funded must be relevant to the supplemented award. However, if a relevant award does not exist because the work to be funded is in a new area, then even available funds are difficult to obligate quickly. In these cases, the project can be initiated first as an award in the IRP, such as with the Molecular Libraries Program. After the project began, ERPs were also funded to launch the coordinating network of extramural screening centers.

With regard to the second criterion, access to unique patient populations or resources, it would be necessary to clarify the specific expertise or population to which the intramural community had access, while the extramural community did not. Without this information, it is unclear whether there is sufficient justification for funding a project in the IRP. This may also lead to questions from the extramural community about the rationale for funding and implementing a program through the IRP.

For example, the NIH Clinical Center clearly has access to unique patients, but may not have access to a broad representation of a specific patient population, which might be more accessible to external clinical centers across the nation. Therefore, when implementing a new program through the IRP, it would be reasonable to require NIH to articulate the unique patient populations and resources that justify a CF investment in the IRP. Further, besides emphasizing what expertise resides within the NIH, a concrete framework based on timeliness and the need for rapid implementation would be useful for deciding which programs should be implemented through the IRP.

A plan such as this would ensure that IRP programs, such as the IPDC, would ultimately be transferred to the extramural community. The Molecular Libraries Program, for example, is an excellent example of how an intramural screening center was integrated into an extramural network of centers that together functioned as a large, coordinated network.

The CFEWG also discussed programs and resources that are considered inherently internal and governmental. The NCBI was discussed as an example of activities considered inherently governmental because of the requirement to develop informatics tools and distribute user-friendly data that are permanently available to the public. However, extramural involvement also could contribute to the process. For example, the data of the Epigenomics Program were housed by NCBI while the computational tools were developed by extramural awardees. By contrast, storage of PubChem data fits the definition of a governmental function, but other aspects (e.g., design, user interface) have been accomplished with extramural involvement, such as through the

BioAssay Research Database project. Therefore, it would be useful to define criteria for inherently governmental projects.

Finally, it appears that IRP researchers are not accustomed to the level of feedback required for CF projects. Intramural staff might also have difficulty adapting to the CF structure, which requires attention to goals and milestones, regular (e.g., quarterly) oversight, and annual financial reports that are often not part of the management of IRPs.

IX. What are the attitudes and level of understanding of NIH staff toward the current planning processes, including how decisions are made? What difficulties in the process can staff identify in order to facilitate greater satisfaction and engagement?

1) Background

Planning, implementation, and management are critical components of implementing Roadmap/CF initiatives, and these are largely conducted by NIH staff. In May 2005, a survey was conducted to assess the NIH staff's opinions of and attitudes towards programs initiated through the CF. The current report again sought staff input through interviews, solicited opinions, and an NIH-wide survey.

2) Findings

A. Strategic Planning

CFEWG interviews of IC Directors elicited comments on various aspects of the strategic planning processes, which were categorized into the following themes: clarity and understanding, budget, and proposal success rate.

Clarity and Understanding. The strategic planning process has been evolving over the last several years. Testing and implementing different methods for strategic planning has generally improved the overall process. IC Directors have been pleased to see their ideas on addressing unmet needs being developed as concepts and funded as CF projects. However, the inconsistency in the strategic planning process has caused some confusion and opacity. This inconsistency could contribute to the submission of ideas too similar to existing CF programs, and could also discourage active engagement in selecting CF programs. In addition, an incomplete understanding or awareness of the current process has made it cumbersome. Further, the variability in feedback on which ideas were selected as CF projects, and why, has had an impact on participation during the Phase 1 submission of ideas in response to solicitations. There was also concern in Phase 2 about the tremendous amount of reading and data analysis, which participants felt could be streamlined. Enhancing the level and regularity of communication and feedback in all of these areas would be well received and appreciated, resulting in even greater participation in the CF planning process.

Budget. The changing budgets available for CF projects during the last several years have also created challenges to the strategic planning process. In practical terms, depending on the annual availability of funds, the number of proposals solicited from ICs could vary from none to two. Working towards consistency in the availability of funds from year to year will contribute to a better appreciation for the CF. Consistency in the budget allocation might also maximize engagement and investment by IC Directors. In fact, the CFEWG heard that more funding for the CF would generate more excitement and enthusiasm for programs.

Proposal Success Rate. Not surprisingly, a successful idea that becomes a CF project promotes satisfaction with the CF. Nonetheless, even ICs that have put considerable effort into developing proposals remain enthusiastic about the CF even if their proposals are not selected. Feedback on what proposals did not succeed, what made them less competitive, and the decision-making process, is particularly important to maintaining enthusiasm for the CF.

B. Decision-Making

CFEWG interviews of IC Directors elicited comments on the decision-making process, which were categorized into the following themes: transparency, input, and involvement in the process.

Transparency. The process by which decisions are made on which proposals become a CF project are not always clear. A clearer understanding of the decision-making process would enhance transparency. Timeliness in informing about decisions would also be beneficial. It is also important to ensure that IC Directors are regularly in the loop about the decision-making process. This engagement will also clarify the role of NIH OD leadership in the decision making process.

Input. Increasing input into the decision-making process is beneficial to CF strategic planning. There was considerable appreciation expressed for how decisions were made on Roadmap initiatives several years ago. At that time, IC Directors were actively engaged in coming up with, vetting, and voting on projects. Comments were made that IC Directors have played a less active role in the process since the creation of DPCPSI, and that program decisions have been made by senior NIH OD leadership with minimal IC Director involvement. There was also a feeling that the lack of feedback on proposals reduced opportunities to provide input. Because of their scientific expertise and experience, the IC Directors should be given the opportunity for full inclusion in the vetting of ideas and discussion, and should provide advice to the NIH Director on which proposals ultimately are funded by the CF. In interviews with IC Directors, it was noted that not all ICs are represented on the CoC, which further distances these ICs from the CF process.

Involvement in the process. There is interest among IC Directors in making substantive contributions in the CF decision-making process, including vetting and debating ideas. The overall success of the CF should benefit from the Directors' scientific expertise and experience. At a minimum, regular updates to the IC Directors about the progress of vetting and development

of ideas into concepts and CF programs would be greatly appreciated. IC Directors would like to feel they have a more active role in a more transparent process, which would enable them to contribute to the formulation of ideas and priorities, communicate recommendations to the NIH Director, and have access to periodic follow-ups about the progress of the initiatives.

C. Role of the NIH Director in the Common Fund

The appropriation of a portion of the NIH budget directly to the OD to support funding of the CF justifies the essential role of the NIH Director in CF processes. The CF is trans-NIH, cutting across the entire spectrum of the NIH mission, and thus mandates a leading role by the NIH Director. The Director's role has also facilitated the innovative nature of the CF. The NIH Director is in a position to not only promote but justify the CF - with justification including regular outreach to ensure sustained and increased funding appropriation. All IC Directors interviewed agreed that the NIH Director has ultimate authority and decision-making responsibility for the CF.

Nonetheless, tactical input from key IC leadership is critical to ensure the most informed decisions. For some CF programs, the NIH Director does receive input from the ACD. However, this level of input alone is probably insufficient, since it can be difficult to build support for programs without broader, grass-roots input. There is interest in greater input and participation by the IC Directors in the decision-making process.

IC Directors' views of their level of input in the CF process range from "significantly involved" to "very little." This input and participation can range from consultation to voting on a project; thus, IC Directors can serve a direct, advisory role on CF projects to the NIH Director.

IC Directors also varied in their opinion about the level of communication received from the Director about the CF, and noted the difficulty in scheduling and identifying the optimum venue and approach for doing so. Nevertheless, they stated that establishing regular interactive communications would be very helpful to the NIH Director.

D. OSC/IC Interactions

The extent and depth of interactions between OSC and IC staff has evolved considerably over time. Currently, however, the primary interaction takes place between an OSC Program Director assigned to a CF program and a Coordinator who is a member of a WG. However, because of changes over time, the purpose, responsibilities and roles embedded in this relationship are not clearly understood by all WG members. For example, some OSC staff might be considered advocates for their CF program, while others might be seen as playing supervisory roles. It is clear that most OSC Program Directors are highly involved and engaged in CF planning and management, and that interactions with WG Coordinators have improved recently, including, for example, greater availability for answering questions and serving as a liaison to DPCPSI and OSC. Program Directors are particularly useful for informing WGs about what is occurring at

DPCPSI, explaining requests and changes, and describing how best to execute the program. The OSC Program Director can also serve as an "early warning system" for the WG: for example, regarding the availability of administrative supplements. In essence, the Program Directors serve as a resource to the WG.

Clearly, unimpeded interactions between OSC and IC's staff are critical to good, bi-directional communication on CF projects. There is general consensus that the level of interactions varies, and this remains a challenge. The quality of interactions also varies; communication is not always transparent, for a variety of reasons. When Program Directors have to deliver difficult news or unfavorable feedback when a program is not doing well, there may be some "paranoia" with regard to OSC.

Also, OSC could improve its documentation of decisions that have been made. Although the CF Handbook was published to provide instruction for WG members to use, many do not refer to it. This can affect the dynamics created by the presence of OSC staff on WGs, which can be quite varied. Increasing WG members' awareness of the content and value of the CF Handbook could be very helpful; for example, many questions can be answered before seeking out OSC staff. Periodic All Hands question-and-answer sessions have been used to present topics of interest to all the WGs. There is concern that Program Directors have numerous responsibilities that might dilute their attention to a particular CF program. The restructuring of the OSC and increase in CF staff beginning in 2007 has begun to help to address this concern, but more help is needed.

Responses from the survey corroborated many of the comments received during interviews of IC Directors. For example, most respondents agreed that current strategic planning processes resulted in carefully considered prioritization of proposed scientific initiatives (agree: 45%, neutral: 29%, disagree: 26%). This result is similar to the 2005 survey (agree: 48%, neutral: 21%, disagree: 31%), although the proportion of respondents who disagreed with this statement declined from 2005 to 2014. In contrast, in 2014, a majority disagreed that the decision-making process for approving CF programs was fully transparent (agree: 18%, neutral: 21%, disagree: 61%). Levels of satisfaction with the overall Strategic Planning process were mixed (satisfied: 36%, neutral: 36%, dissatisfied: 28%), and fewer were satisfied with strategic planning and decision making processes now than in 2005 (satisfied: 42%, neutral: 28%, dissatisfied: 30%). Further, feelings were mixed with regard to the level of satisfaction about the decision-making process for the approval of proposals to become CF programs (satisfied: 35%, neutral: 33%, dissatisfied: 32%).

Nonetheless, respondents were two and a half times more favorable than unfavorable about their personal level of participation in the planning process. A majority of respondents were satisfied with their level of participation (satisfied: 52%, neutral: 28%, dissatisfied: 20%).

A sizeable majority of participants responded that they were satisfied when asked about both their individual level of participation (satisfied: 71%, neutral: 18%, dissatisfied: 12%) and that of their ICs (satisfied: 66%, neutral: 20%, dissatisfied: 13%) in CF programs after WGs are formed.

The majority of participants expressed satisfaction with the process of refining broad program ideas into specific initiatives (satisfied: 63%, neutral: 25%, dissatisfied: 12%).

Interviews with staff suggest that these survey findings of overall mixed feelings with regards to strategic planning and decision-making compared to the very high level of personal satisfaction with individual participation in the process likely reflects whether the survey respondent was a member of a WG, especially for a well-run and successful CF program. Staff from ICs whose ideas emerge into concepts and ultimately CF programs are more likely to be satisfied with the process than those whose ideas are not successful, especially if there is less than adequate feedback on unfavorable decisions.

Recommendations for Strategic Planning

Recommendations for Phase 1 Planning

RECOMMENDATION 1: ***Enhance efforts to educate and inform the scientific community about the purpose and goal of the CF.*** With several CF projects now well underway and making significant progress toward meeting expectations, it is possible to demonstrate evidence of the value of CF investments. Greater awareness of the CF and the benefits to the nation from CF investments will increase appreciation for the CF and broaden interest and engagement. More information on "gaps" that CF initiatives intend to address should be provided.

RECOMMENDATION 2: ***Revise the solicitation process in Phase 1 planning to broaden the diversity and scope of input without overburdening the process with ideas that are irrelevant and inappropriate.*** For example, enhance opportunities for broad community input and pick a number of ideas from that process that have the potential to be developed as CF programs. Some of these ideas could emerge from ongoing, non-CF-related trans-NIH discussions that could be supported with limited investment, and could engage the broader research community through workshops and symposia. These ideas could then be further developed before submission as a CF concept for consideration by Council and NIH leadership. OSC staff should be included in the internal input process of Phase 1 planning.

RECOMMENDATION 3: ***Evaluate what has worked well, and what has not, in the process for soliciting ideas and concepts internally from ICs and externally from participants at expert meetings, and improve the process where possible.*** For example, OSC should conduct a formal, annual “launch” of a new round of CF solicitations, including an announcement and presentation at a meeting of IC Directors. The presentation could include a summary of highlights of current CF programs, especially noting those recently adopted, and acknowledging those ICs playing key roles.

RECOMMENDATION 4: ***Clearly articulate the purpose and goal of the CF to participants in expert meetings to maximize the relevance of ideas generated.*** Also, clearly present downstream processes: specifically, how the ideas will be considered further, and the process for

deciding how a concept becomes a CF program. Create a document describing outreach activities to notify people of the purpose and goals of meetings. To continue building enthusiasm for and engagement in the process, participants should come away from strategic planning exercises feeling that their voices have been heard, and understanding the context in which ideas are developed, and how the ideas will ultimately be processed, evaluated, and potentially adopted.

RECOMMENDATION 5: ***Enhance and refine the existing Phase 1 planning processes to maximize the effectiveness of gathering input from external and internal sources during the allotted nine months, including developing different approaches and mechanisms for external meetings of experts.*** For example, scheduling a meeting around a large national conference broadens the diversity and perspective of potential invitees. Another possibility is a more continuous, ad hoc approach to Phase 1 strategic planning, which would allow ideas to incubate and arise spontaneously in response to a changing research landscape. Allow interactive retreats and collaborative initiative in concept development. Develop a "crowd-source" approach to capture ideas from individual staff that could be used as "wild card" spots in Phase 1 strategic planning. Ideas generated more dynamically and in real-time, from within or outside NIH, could enhance the process. Provide OSC funds for workshops and staff time to develop the proposals.

RECOMMENDATION 6: ***Draft guidelines that formalize the process for articulating and developing ideas so that they are presented in a "Common Fund-able" way.*** OSC should establish clearly articulated criteria for deciding which ideas to move forward and be developed into concepts that are ready for presentation to CoC - a process that some interviewees referred to as "programifying" the concepts. These guidelines should consider related factors, such as revising ideas for consideration during a later round. This will ensure that all sufficiently compelling ideas are presented to CoC. In turn, CoC can act as a public, extramural filter, clearing concepts for consideration by the NIH leadership, including IC directors, for transition to Phase 2 strategic planning.

RECOMMENDATION 7: ***Establish other approaches, including a CF pilot project process, that could enhance flexibility in the CF strategic planning process for determining which ideas warrant additional investment.*** For example, a one- or two-year pilot opportunity may provide sufficient evidence to inform a project's potential for additional CF funding. Such new approaches should align with the mission, purpose, and goal of the CF.

RECOMMENDATION 8: ***Establish mechanisms that allow more flexibility for managing the development of concepts and refining concepts into program proposals.*** Irrespective of their innovative potential, not all ideas can be expected to develop at the same rate. Therefore, a process for "recycling" or extending ideas for further consideration of their potential in a timely fashion should be developed in concert with all stakeholders. The prioritization process serves an important role in this process, and should not be circumvented.

Recommendation for Rapid Planning for Urgent Needs

RECOMMENDATION 9: ***Define criteria and establish a standard operating procedure for rapid responses to emergency challenges and opportunities that are consistent with the CF purpose and goal and justify CF investment.*** Specific, targeted, and well-characterized criteria are needed to: 1) determine if a concept actually meets the CF criteria; 2) allow the CF to consider other incidents that may qualify but have not been considered (e.g., Hurricane Sandy); 3) provide justification for the decision by the NIH Director, and 4) enable the emergency concept to be prioritized within the regular CF strategic planning process. It is possible that the routine process might not be fast enough, and a separate process for emergency challenges might be needed.

Recommendation for CoC Review

RECOMMENDATION 10: ***Review and revise procedures by which the CoC reviews and assesses concepts for clearance, including developing and articulating guidelines for the criteria used to eliminate or modify ideas before being sent to the CoC for clearance.*** Establish certain milestones that help to quickly prioritize which ideas should advance further with additional input. For example, an abbreviated portfolio analysis could be initiated for some ideas that are advancing. These additional activities could happen simultaneously as internal input is received. Establishing small targeted groups of external experts to implement this revised process could filter out irrelevant and/or inappropriate ideas early on so that the time available could be better spent on stronger proposals.

Recommendations for Phase 2 Planning

RECOMMENDATION 11: ***Establish and articulate the process by which cleared concepts develop and progress into CF programs.*** A major factor affecting the clarity of goals and milestones for a program is how clearly and faithfully a concept is transformed into a CF program. Additional guidance on transforming concepts into programs, emphasizing the importance of establishing clear goals and milestones, would help ensure a common understanding of the program objectives. Establishing a regular rhythm of clearly articulating and regularly emphasizing those goals and milestones should also facilitate understanding and appreciation of individual CF programs.

RECOMMENDATION 12: ***Ensure sufficient time and resources are available for comprehensive and consistent portfolio analyses.*** The quality of the portfolio analysis is another vital factor impacting the clarity and relevance of the goals and milestones for a new program. Suggestions include refining the knowledge management and Information Technology resources for portfolio analysis, and ensuring that staff have adequate time, resources, and support to conduct the portfolio analysis appropriately.

RECOMMENDATION 13: ***Clearly define and clarify the roles and responsibilities of OSC and WG members in Phase 2.*** This should be coupled with enhancing collaboration and

communication, which will naturally enhance the transparency and consistency of decision-making and prioritization processes when moving an idea to a concept. Emphasize regular communication between OSC and WG members, including increased feedback on approvals and rejections of ideas and concepts, the importance of clear goals and milestones, and progress on concepts cleared for further development. Develop alternate ways to recruit WG members who will remain actively engaged.

RECOMMENDATION 14: ***Provide more opportunities for IC Directors and the CoC to enable sufficient feedback on concepts that are being developed in Phase 2***. Encouraging feedback may ensure greater buy-in and better-developed concepts. This might also facilitate greater cross-IC collaboration (or earlier planning for it) when an IC Director gets involved and may wish to contact another IC Director, either directly or via staff, about a proposal that is moving forward.

RECOMMENDATION 15: ***Ensure sufficient representation on the CoC or a subcommittee of CoC to enable all ICs to participate in Phase 2.*** For example, representation by all ICs on the CoC, even on a rotating basis or in rotating ad hoc membership (e.g., without vote unless they rotate into a full member role), would allow more involvement in all phases of the strategic planning process. A CoC subcommittee could facilitate communication between OSC and CoC with regard to CF programs under development.

RECOMMENDATION 16: ***Ensure greater transparency/clarity surrounding the process by which programs exit Phase 2 as funded CF programs*****.** Greater transparency would lead to increased participation by IC Directors in submitting candidate projects. To facilitate transparency, there should be regular communication between OSC and IC Directors and staff regarding approvals and rejections of ideas and concepts, progress on project development, and the need for continued input regarding candidate projects.

RECOMMENDATION 17: ***Streamline and clarify the steps for selecting Phase 2 ideas and developing them into program proposals***. Greater process efficiency would facilitate more effective and productive participation by IC Directors and NIH staff. The precise steps for selecting and developing candidate CF project ideas are not clear. If the process is unambiguously laid out, straightforward, and smooth, it should be easier to productively engage IC Directors and their staff, whose input and shared expertise would enhance project development and increase the chance of success.

Recommendation for Intramural-only CF Programs

RECOMMENDATION 18: ***Develop a concrete framework for when a program is suitable for an intramural-only program, including further clarifications regarding the criteria.*** Components of this framework should include the following:

- For projects requiring rapid implementation, include a justification based on clear criteria specifying why the program must be an IRP.
- Mandate that NIH clearly articulate the unique patient population or resources for which it can justify implementing a new program or initiative through the IRP.
- Determine which aspects of programs are inherently governmental, and which aspects are not. For example, warehousing data in a place that must be accessible to the public may be an inherently governmental function, but developing the user interface to access that data may not be.
- Determine the extent to which IRP programs should be reviewed and cleared through advisory councils within the NIH, similar to the way extramural programs are vetted. Also, determine the extent to which the CoC should be involved in IRP decisions.

Recommendations for Communication and Input

RECOMMENDATION 19: ***Develop a mechanism to increase IC Directors' input to the OD in decision-making on CF programs.*** A meeting with IC Directors just before each year's CF programs idea solicitation process might engage them more actively and communicate that their input and participation is valuable. While a direct meeting would be preferable and more effective, written or voice communication would also include IC Directors more explicitly in the process. Once candidate CF projects are identified, discussions with IC Directors with expertise in specific topics would also enhance their engagement.

RECOMMENDATION 20: ***Improve communication and working relationships between OSC and IC staff developing CF programs.*** The success of CF programs depends absolutely on clear communication between OSC and IC staff, along with strong engagement of staff members working on the CF programs. Communication should specify the respective roles of OSC and IC staff members, with the underlying assumption that OSC and IC staff will work together as collaborators, rather than as supervisors and employees. This kind of transparency is critical to effective project management and outcomes.

RECOMMENDATION 21: ***Communicate as early as possible the availability of funds to support new CF programs.*** If Directors, researchers, and staff know well ahead of time how much funding is available to support the CF each year, they will likely find it easier to propose and evaluate potential programs. We recognize that budgets vary from year to year, but it may be that if IC Directors and staff know in advance that some minimum amount or percentage of the annual budget will be available for CF programs, they will feel more comfortable about investing time and resources in planning, knowing that there is a good chance of several programs being funded.

2. COMMON FUND MANAGEMENT PROCESSES

The CF is coordinated by the OSC, one of the nine offices of the DPCPSI within the NIH OD. NIH ICs work with OSC on the design, implementation, and evaluation of CF programs. This OD-IC partnership enables central management and oversight of the CF programs while also tapping into the vast knowledge and expertise throughout the ICs. Funding approval is provided by the OD, and this information is then conveyed to program, grants management, budget, communications, policy, and evaluation staff throughout the NIH. In all of these areas, OSC staff coordinate and liaise with the larger IC communities.

According to the CF Handbook and the NIH website, all CF programs follow a similar structure, with management by NIH staff and oversight by the assigned OSC Program Director. This creates a uniform way to capture and present data across all CF programs. The CF comprises numerous programs, each managed by a trans-NIH WG. WGs oversee the development and implementation of CF programs and identify emerging issues related to their area or topic that may warrant revisions to their program.

Program management in the context of CF programs encompasses implementation of the program design as conceived by the WG; the creation and issuance of funding announcements; oversight of program performance; and examination of program impact. Once a new CF program has been officially approved by the NIH Director, the WG formulates detailed implementation plans. The WG establishes goals and milestones to organize its plans and activities and to set benchmarks against which program progress can be measured. FOAs and Requests for Proposals (RFPs) are created based on these goals and milestones. The WG oversees the management of CF programs in both the pre- and post- award phases, communicating regularly with the OSC Program Director to keep OSC informed about progress and new developments.

Reporting. The OSC asks each CF WG to complete an Annual Progress Report at the start of each fiscal year. The purpose of the report is to track the program's progress, explain any issues that WGs encountered, and propose plans for the upcoming fiscal year. The template for the progress report is sent to the WGs, who have approximately four weeks to prepare and submit the report. The Annual Progress Report is developed through conversation with the OSC Program Director, who reviews the document first and may ask the WG to clarify certain sections. The reports are then reviewed by the Directors of OSC and DPCPSI, who may approve the WG’s proposed plans as submitted or may approve with modifications. If concerns are raised, or if substantial changes are proposed, OSC/DPCPSI generally meet with the WG leaders prior to finalization of the annual budget.

WGs are expected to measure the effectiveness of their CF program using the goals and milestones laid out in the FOAs. Additionally, WGs assess changes in the scientific environment, dissemination of program outputs, capacity building, and the degree to which the program has focused on the most pressing scientific needs.

I. Are expectations for programs clearly articulated in funding announcements, program kick-off meetings and documents, websites, program materials? Are the goals and responsibilities clear?

1) Background

Development of FOAs. The process of developing and approval of FOAs is described in the CF Handbook, so only a short overview is provided as background. When a CF program is approved by the NIH Director, an OSC Program Director is assigned responsibility for the program and works with the ICs who generated the program, and establishes a WG. The WG designates a Project Team Leader and Chief GMO for the proposed FOA, usually from the IC that will administer the FOA, with concurrence from the relevant IC Director. The Project Team drafts the FOA for the entire WG to review. Communications regarding the development of the FOA should come from either the Project Team Leader or the WG Coordinator. Once the FOA is drafted and approved by the WG, it is sent to the OSC Program Director for feedback on the draft FOA language. After feedback is incorporated, the FOA is reviewed and cleared by the WG and WG Co-Chair, and obtains the approval of the lead IC Chief, GMO, or designee. The final draft of the FOA and all supporting documents are then sent to the OSC Program Director to obtain OSC approval. The OSC Program Director reviews the FOA to ensure that it falls within the approved budget and meets the overall intent of the approved CF Program.

The CF Handbook states, "*OSC strongly encourages WGs to develop post-award management strategies before FOAs are developed*"; however, there is no detail on how to "kick off" CF programs or how to establish steering or external review groups.

2) Findings

The CFEWG reviewed materials used in program kick-off meetings, FOAs, and program summaries. Five programs were reviewed for each of these categories; the documents reviewed are listed in the discussion of each category. Additionally, the CF Handbook was reviewed for procedures of FOA development and approval and grants management. Finally, interviews with IC Directors, IC staff, and OSC staff, and review of the 2014 survey, informed the CFEWG's findings.

FOAs. FOAs for five programs (see Appendix 16) were used as background on program expectations, including programs developed early and later in the CF program:

1) Molecular Libraries and Imaging (ML)
2) PROMIS
3) National Centers for Biomedical Computing (NCBC)
4) Epigenomics
5) Human Microbiome Project (HMP).

The CF program FOAs for the ML, initiated in 2004, were among the first FOAs developed. A number of FOAs were released that described the different aspects of the program. The ML was designed as a scientific resource to accelerate the discovery of protein functions that control processes critical to health and to any disease. This program was expected to have a very high impact by facilitating understanding of basic biological mechanisms, identifying new biological targets for evaluation in disease models, and shortening the timeline for ligand and tool discovery. The Molecular Libraries (Screening Centers Network) FOA contained a detailed Research Objectives section with expectations for establishing the Pilot Centers, the structure of the Molecular Libraries, and the expectations for each of the centers. This FOA also contained a description of interactions and oversight by the NIH staff, and specified that all data would be in the public domain.

The FOAs for the early CF programs initiated in 2003/04 are very different from the more structured FOAs for the 2007/08 CF Programs. The FOAs for the National Centers in Biomedical Computing program (NCBC, released in 2003) and the PROMIS program (initiated in 2004) described wide-ranging scientific objectives for the program and complex infrastructures, with an "approximate" timetable for accomplishing goals. For example, the PROMIS FOA included an overall structure comprising a cooperative network of Primary Research sites, a single Statistical Coordinating Center, a Steering Committee structure that included the NIH Science Officer and the PIs of the Research Centers, and an external Scientific Advisory Board to review and make recommendations. While the timetable provided milestones and goals, these were not specifically defined as goals or expectations to be used in making decisions or recommendations. A three-year review by an external committee of the PROMIS Program *"...concluded that the program had met its goals for the first three years but the panel also commented that the ultimate success of the project would depend on accomplishment of three key milestones."*

Two more recently developed FOAs for CF projects initiated in 2007, the HMP and the Epigenome, followed more uniform formats, featuring sections on the Nature of the Opportunity, Background, and Research Objectives. Later FOAs focused on transformative discoveries with objectives that were expected to significantly advance the field. While specific metrics were not defined, the broad scope of the research was emphasized and the areas of investigation (and those that were not within the program scope) were also well described. For these CF programs, multiple FOAs were released to leverage different grant mechanisms. The HMP, for example was envisioned as a five- to six-year program and was highly successful at meeting or exceeding its milestones; and the broader community rapidly expanded microbiome research in many new and exciting ways. FOAs for both the Epigenome and HMP programs provided clear research goals that aligned with the purpose of the CF programs.

Kick-off meetings. The CFEWG reviewed kick-off events for five CF programs:

1) Science of Behavior Change
2) Extracellular RNA Communication
3) Strengthening the Biomedical Research Workforce
4) Human Microbiome Project (HMP)
5) Library of Integrated Network-Base Cellular Signatures (LINCS)

The CF kick-off meetings took one of two approaches. The first approach, used during the kick-off meeting for the Science of Behavior Change program, was a scientific symposium with research presentations by PIs as well as experts in related fields. The symposium agenda did not include information about the CF program; nor were there any agenda items about the process by which the program PIs would collaborate or be reviewed.

The second approach, used for the other four programs reviewed, started with an OSC or IC Director speaking about the CF Program, and included discussions on operations and evaluation. At the Extracellular RNA Communication kick-off meeting, the ESP was present and introduced, and discussion items included the scope of the programs, the responsibilities of the PIs and NIH staff, and evaluation criteria. In addition, most of these kick-off meetings included sessions on establishing collaborations and criteria for studies. Some kick-off occasions were two-day meetings that included scientific presentations. This latter approach appears to be a best practice for kick-off meetings, as this model enables the OSC Program Director and the WG to fully discuss programmatic expectations, establish relationships, and address questions.

Program summaries. The WG reviewed summaries from the following five CF programs:

1) PROMIS (see Appendix 17)
2) ML (see Appendix 18)
3) NCBC (see Appendix 19)
4) HMP (see Appendix 20)
5) Epigenomics (see Appendix 21)

Program summaries included descriptions of program frameworks and management. Of the programs reviewed, the CFEWG selected two - Epigenomics and HMP - as examples of clear expectations and effective management strategies to support accomplishment of the goals stated in their FOAs. The Epigenomics WG was established with leadership from NIEHS and NIDA. The Director of the National Institute on Deafness and Communicative Disorders (NIDCD) joined later as a third Co-Chair. This WG consists of representatives from 19 ICs and is responsible for review, modification, and recommendation of changes to the original Epigenomics project plan. Additionally, the WG program leadership is informed by the activities of the International Human Epigenome Consortium (IHEC). Two program staff members from NIDA and NIEHS serve as representatives to the IHEC Executive and Scientific Committees.

The first phase of the HMP was managed by a large trans-NIH WG, co-chaired by four IC Directors and comprising program staff from nearly every IC. The HMP WG Coordinator was responsible for overall programmatic oversight and coordination, including organization of the HMP research network consortium that included hundreds of researchers, some of whom were not supported by the HMP. The HMP Coordinator also played a key role in organizing and coordinating the International Human Microbiome Consortium.

The HMP scientific Co-Chairs and the HMP WG advised and approved major programmatic decisions and funding recommendations. From HMP's onset, OSC staff were involved in overseeing progress and helping to ensure success of the program. A steering committee consisting of NIH HMP WG members and both intramural and extramural HMP-funded PIs addressed issues affecting project progress, meeting milestones, and other factors relevant to completing the work set out in the FOA. For Phase I, a panel of seven scientific consultants, known as the External Scientific Consultants (ESCs), who were neither HMP grantees nor consortium members ESC members, attended annual HMP network consortium meetings and provided advice to the NIH Working Group on a frequent basis. The ESC also reviewed the progress of the grantees and participated in the midcourse review of the program.

Results from the 2014 NIH CF Evaluation survey and the 2005 Roadmap Survey were reviewed to assess the process for developing FOAs and funding plans. One survey question asked whether "*...the process for developing FOAs for CF programs is clear,"* and the majority of respondents agreed (agree: 58%, neutral: 19%, disagree: 23%). These responses were slightly more positive than those from the 2005 survey (agree: 50%, neutral: 24%, disagree: 26%).

The 2014 NIH CF Evaluation Survey asked if "*...there are clear procedures for establishing the funding plan*," and the majority of respondents agreed (agree: 66%, neutral: 19%, disagree: 16%). Comments from both the survey and the interviews with WG members indicated that the process was clear, but provided suggestions for developing a better orientation processes for new WG members. A majority of respondents agreed that the CGMO at the lead IC was involved at an appropriate point in the FOA development process (agree: 51%, neutral: 32%, disagree: 18%). Despite the survey results, we conclude that it is important for the grants management staff to be involved earlier in the FOA process, based on responses to interviews with WG staff. Survey responses indicated that a majority of respondents agreed that OSC staff provided timely guidance during FOA development (agree: 55%, neutral: 27%, disagree: 18%). During interviews, WG members commented that relationships with OSC staff have evolved since 2007. Respondents noted that most OSC staff have more experience in providing guidance now, and also communicate more effectively the expectations of OSC and how to meet them.

Interviewees from OSC staff and WGs made two important points about management of CF programs. First, the OSC Program Director should provide an orientation for WG members to facilitate all phases of CF program management. Interviewees suggested including experienced WG members in the orientation as a mechanism for sharing lessons learned from other CF programs. Second, there is a need for more effective communications; both groups of

interviewees expressed some dissatisfaction with the clarity and timeliness of communication between WG and OSC. OSC staff said that they did not routinely communicate how or when decisions affecting WG management and budget were made.

Are the goals and responsibilities clear?

The FOAs that the CFEWG reviewed had clearly stated programmatic goals. However, the responsibilities of grantees and WGs were less clearly defined. In some of the kick-off meetings, discussion of goals and responsibilities was a central focus. During interviews, OSC staff respondents commented that WGs that develop strong FOAs and establish effective WG structures were able to make the goals and responsibilities of the PIs and WGs clear. WGs and CF programs that did not clarify these elements were less effective overall.

Reviews of five CF Program summaries (particularly the sections on external evaluation of the program and challenges) provided information on the clarity of goals and responsibilities of awardees and NIH CF staff. A recurring challenge in multiple CF programs was that PIs focused on their own interests rather than on programmatic goals. Additionally, the goal of collaboration inherent to CF Programs was either not made clear or not effectively managed by the program steering committee or the WG. This suggests that CF goals and responsibilities were not uniformly made clear to PIs.

II. Are evaluative processes sufficient to provide critical assessment throughout the program's lifespan?

1) Background

The CFEWG reviewed the Evaluative Processes document (see Appendix 22), the five program summaries, and the CF Handbook. The Handbook describes how OSC monitors the progress of CF programs and provides information for WGs on how to measure program effectiveness. Specifically, the Annual Progress Report provides WGs an opportunity to:

- Review their goals and milestones and answer questions from their OSC Program Director
- Describe progress and challenges in meeting goals and milestones in the past year
- Articulate plans for the coming year
- Describe issues encountered in program management (including those encountered by PIs)
- Report on emerging issues in the field that their program supports and whether the program should be modified to respond to those issues
- Provide information on new tools or publications produced through the program
- Update OSC on changes in WG membership or leadership
- Describe new requests for additional funds or supplements.

According to the CF Handbook, a program evaluation is a systematic study conducted periodically or on an ad hoc basis to assess how well a program is performing. It involves the collection of information about the activities, characteristics, and results of a program. It is often conducted by experts external to the program as well as by program managers. Below, common types of evaluations are described.

- *Assessment of needs, gaps, and opportunities.* In the planning or early implementation stage of a program, the purpose of this evaluation is to assess the magnitude of the need and identify gaps in knowledge, services, products of research (e.g., tools and technologies), training, and resources. Later on in program implementation, the purpose is to determine if there is a need to extend the program beyond its originally funded period, update the baseline in response to changes in external influences, and assess whether the community is satisfied with the program's services and outputs.
- *Process evaluation.* This form of evaluation examines the extent to which a program is operating as intended. It typically assesses the program's alignment activities with statutory and regulatory requirements, program design, and professional standards or customer expectations. Programs that are trying a new funding mechanism will typically conduct a process evaluation.
- *Outcome evaluation.* This assesses the extent to which a program achieves its outcome-oriented objectives. It focuses on outputs and outcomes (including unintended effects) to judge program effectiveness, but may also assess program process to understand how outcomes are produced.
- *Impact evaluation.* Impact evaluation focuses on the program's net effect by comparing program outcomes with an estimate of what would have happened in the program's absence. This evaluation is employed to isolate the program’s overall achievement when external factors are known to influence the outcomes.

According to the CF Handbook, evaluations of CF programs are recommended when the program continues or ends; when an evaluation would enhance programmatic goals; and when requested by OSC.

2) Findings

Reviews of interviews with WG members and OSC staff made it clear that Annual Progress Reports were seen as important, because they identify strengths and weaknesses in CF programs and enable WGs to make a case for changing priorities and/or reallocating resources. However, interviewees commented on the lack of clarity on what OSC Program Directors expected from Annual Progress Reports, and said that there needed to be discussions between the WG and the OSC Program Director to support development of evaluative and actionable reports. OSC staff noted that WGs do not have an incentive to complete useful and informative Annual Progress Reports. On the other hand, well-written progress reports can act as good "advertising" for CF programs. It is important to remember that the OSC Program Di rectors use Annual Progress Reports to update the Director of OSC, and the Director of DPCPSI. The Director of OSC and DPCPSI can then update the Director of NIH with that information.

Some WG members appeared confused or unclear about the evaluation requirements for CF programs. Both the WG members and OSC Program Directors noted that there was a tension between conducting innovative science and micromanaging progress and milestones.

III. Are goals and milestones met?

1) Background

Goals and milestones for the CF programs are part of the FOA and are also emphasized and discussed in some of the kick-off meetings and documents.

2) Findings

The CFEWG reviewed five program summaries to assess the degree to which programs met their goals and milestones. The CF Programs that the CFEWG reviewed were uneven in meeting the original targets set forth in the FOAs. For the more recent projects, when the FOAs had clearly articulated goals and milestones as with CF Programs initiated in 2007 and later, the likelihood of meeting targets was higher. In addition, the value of the kick-off meetings and documents was variable; when the kick-off meetings and documents included clearly articulated goals and milestones and outlined the responsibilities of the PIs, the likelihood of reaching the goals and milestones was higher. In interviews, OSC staff voiced the opinion that when a program does not have clearly articulated goals, the program struggles.

IC Directors who were interviewed generally supported the CF programs and said that they had value for the IC and IC staff. However, they said that the success of the CF programs was uneven, some showing great success in their innovation and achievement of articulated goals, and others providing value but not as successful. Overall, the IC Directors largely supported the CF programs and saw them as successful in meeting their goals and milestones.

IV. Are management processes flexible and adaptive to changing scientific landscapes?

1) Background

The CFEWG reviewed examples of changes in the scientific landscape that were made in five programs: Epigenomics, HMP, PROMIS, ML, and Single Cell Analysis (see Appendix 23). To help answer this question, the group also reviewed the CF Handbook sections on Budget and Management. Although a general budget plan is developed by the WG when the program is launched, adjustments are often necessary for various reasons. The WG can make decisions about how funds are allocated among the initiatives and sub-initiatives in a program. A portion of each WG budget may be apportioned to Research Management and Support to support staff salaries and benefits, travel, contracts, meetings, and other expenses.

The WG maintains flexibility to move money between sub-initiatives, but a change of greater than 10% from the previously planned budget for a specific sub-initiative requires a justification to OSC. This justification should be provided in the text of the Annual Progress Report that accompanies the operating budget. Requests for additional funds may be made and should be compellingly justified in the Annual Progress Report.

2) Findings

As examples of program changes made because of the changing scientific landscape, synopses of the five CF Programs named above were provided for review by the CFEWG. Changes took the form of additional funding for new initiatives or continued funding for the second project phase to address new developments in the field; allowing data to be accessed more easily; or validating earlier results.

For example, a sixth initiative was added to Epigenomics to address the fact that manipulation of the epigenomes largely relied on pharmacological or genetic manipulation of epigenetic regulatory proteins. Similarly, at the end of the first phase of the HMP program, NIH leadership decided to build upon first-phase results by supporting the program for three more years with a more focused initiative. A new initiative was added for the program's second phase, to create a community resource that can be used to decipher the role of the microbiome in human health.

Management of CF programs through the WG structure is the responsibility of the IC staff who typically perform this duty in addition to their other IC responsibilities. Most IC staff interviewees value their involvement in the CF program WGs; respondents said that they valued the CF programs themselves as well as the opportunity the WGs provided for cross-IC interactions. Conflicts arise when additional temporary staff are required to manage CF programs. Since CF programs have term limits, ICs prefer to hire temporary instead of full-time staff so that their positions can be terminated at the end of the program. This poses problems for recruiting individuals with appropriate expertise who agree to work in temporary positions. Discussions with OSC staff indicated that there are limited solutions, such as granting greater flexibility to the use of contractors, or allowing staff employees to be shared between ICs.

Interviews with WG members revealed that management of CF programs had evolved, as had the involvement of the OSC staff. While interactions with the assigned OSC Program Directors were beneficial overall, many WG interviewees complained about the increasing bureaucracy. As an example, even insignificant changes in the budgetary process had to be approved by OSC staff. These interactions were time-consuming, as confirmed by OSC Program staff.

The CFEWG reviewed the 2014 NIH CF Evaluation Survey to examine adaptation to changing scientific landscapes. The survey asked respondents about the past response to changes in the scientific environment. Most agreed that OSC allows for rapid response (agree: 40%, neutral: 36%, disagree: 25%). Respondents were also asked their opinions on aspects of budgetary

guidance. The majority of respondents agreed that current budget management processes for CF programs work well (agree: 54%, neutral: 36%, disagree: 9%) and that budgetary guidance provided by OSC is clear (agree: 57%, neutral: 26%, disagree: 17%). A majority of respondents felt that this guidance is timely (agree: 53%, neutral: 34%, disagree: 13%), and most respondents agreed that CF Budget Reports currently available to ICs are helpful (agree: 58%, neutral: 27%, disagree: 15%). A plurality of respondents agreed that the procedures used to develop the annual operating budgets are clear (agree: 45%, neutral: 30%, disagree: 25%). Most felt that the procedures used for developing FTE loans are clear (agree: 47%, neutral: 32%, disagree: 21%).

Written comments from survey respondents and interviews provided additional insights. In general, respondents commented that CF budget processes are working well and that communication with OSC works well. Several respondents recommended simplifying and streamlining the budget processes. A suggestion was made that to streamline the submission process, there should be a meeting with IC BPOCs, OSC Budget staff, and WG leadership before budgets are due. Another comment was that OSC should allow more budget flexibility for absorbing small budgetary changes. A suggestion was made that consistent terms should be used for budget processes across NIH.

V. What should the process be for management of intramural-only programs?

1) Background

Descriptions of intramural-only programs are provided in the CF Handbook—for relevant examples see Appendix 24. Most CF award solicitations are open to applicants from all organizations, including the NIH Intramural Research Program (IRP), as a way of supporting the best science regardless of where the research is conducted. Occasionally, programs are identified that are awarded to intramural investigators without competition. An intramural-only program (or initiative) is one that resides solely in the NIH IRP. It is designed from the start to receive CF dollars dedicated to the IRP, and does not compete with extramural applications for funding. An intramural-only program is developed by a multi-IC WG comprising IRP scientists and/or Extramural Research Program (ERP) staff who have the appropriate expertise. The WG is to engage all available resources in developing the program, including existing trans-NIH groups (interest groups, committees, and other groups), other related IRP research activities, and extramural investigators through workshops and other avenues.

In these programs, IRP projects are subject to the same planning, application, review, and oversight processes that are used for extramural awardees. The CF handbook specifies that when managing intramural-only programs, the WG must seek the input of the scientific communities both inside and outside of the NIH. This may be done in many ways, including:

- An ESP comprising extramural scientists that provides guidance on how to better serve the community

- A body of NIH Program Directors who can advise the WG Group on whom to collaborate with in the extramural scientific community
- A committee of IC Scientific Directors who can advise on intramural collaborations and resources
- An annual meeting during which scientific progress is shared and discussed and a meeting report is generated. If this option is included, the external scientific panel should be present to provide recommendations to the WG.

When the goal of the program or initiative is to develop a resource for the research community at large, oversight should include frequent interaction with users (or potential users) in both the IRP and the ERP.

2) Findings

The CFEWG reviewed examples of intramural-only programs, including the GuLF Study and PubChem, Imaging Probe Development Center, Clinical Research Training Program, Epigenomics Data Management, and NIH CRM (see Appendix 24). These programs benefit from the unique composition and management of the Intramural program, although how the NIH is uniquely composed to facilitate these programs is not explicitly stated and is not always obvious in a given program. The programs may involve Working Groups, internal and external advisory committees (see above), and evaluation at various levels according to the program.

The section on Intramural Involvement in CF programs from the CF Handbook was reviewed to examine processes of intramural-only programs. We noted that it was difficult to obtain detailed information on the management process of IRP-only programs, and this question was not covered on the 2014 survey. Moreover, in cases where there was some information on the management process, it was unclear how or why a particular process was chosen and pursued.

IRP-only programs are managed differently from other extramural CF programs, likely as a consequence of the goals and intent of the programs. The success of these programs varies, largely because of oversight and differences between the original project goals and those of the intramural PI. In some cases, the IRP-only programs have not worked effectively (i.e., not met programmatic goals) and other strategies have been employed to achieve the stated aims.

VI. Are OSC/IC interactions working well?

1) Background

Once a CF program is approved, OSC Program Directors have a short orientation meeting with the WG leadership. There is one OSC Program Director assigned to each CF program, and OSC Program Directors are responsible for more than one CF program. During the course of funded programs, the WG members interact with grantees. WG members are the liaisons between the ICs and the OSC.

2) Findings

To assess interactions between ICs and OSC, results from the 2014 NIH CF Evaluation Survey and interviews with OSC staff and WG members were reviewed. Participants in the survey generally expressed positive views regarding OSC communication and guidance. A plurality of survey respondents agreed that the OSC provides adequate governance for CF programs and activities (agree: 48%, neutral: 32%, disagree: 20%). A majority agreed that the OSC promotes a collaborative environment (agree: 56%, neutral: 26%, disagree: 18%). Similarly, the majority of respondents felt that OSC promotes communication among IC staff (agree: 55%, neutral: 34%, disagree: 11%). Overall, the survey respondents generally feel that interactions between ICs and OSC are collaborative and work well.

Interviews showed some variability in interactions with OSC Program Directors. Some WG members reported that Directors are very involved and easy to interact with, whereas others reported more difficult relationships. The CF program staff and ICs do not necessarily know what the expectations of the OSC Program Directors are in terms of interactions with OSC. Moreover, some OSC staff support five or six programs, which makes it difficult for them to participate in all WG meetings. Generally speaking, NIH staff commented that OSC roles could be more clearly defined, including the organization of OSC.

There was uniform agreement that the workloads of staff dedicated exclusively to CF Program activities within the ICs should be considered, because it is difficult for WG members to balance an IC program officer's workload with CF program management. For example, at the end of the fiscal year, the OSC requires a substantial amount of information from the WG staff, and the exact format and content is not clearly communicated. Also, it is generally felt that at the end of a CF program, grantees are expected to transition to IC funding, and the mechanism for this transition should be better defined by the OSC.

VII. Is the Working Group structure meeting the management and oversight needs of the programs?

1) Background

The CF Handbook section regarding Working Groups and Roles was reviewed to assess the degree to which the WG structure is meeting the management and oversight needs of CF programs. The CF Handbook describes the WG structure extensively. WGs oversee the development and implementation of CF programs and identify emerging issues related to their area/topic that may warrant revisions to their program. The WGs will sometimes delegate these duties to Project Teams that focus on specific initiatives within their program. The WGs operate under the direction of their Co-Chairs and are managed on a day-to-day basis by the WG Coordinator.

To ensure a multi-IC perspective for each program, each WG includes at least two IC Directors or very senior program staff who will serve as Co-Chairs; several program representatives from multiple ICs; and budget and grant management points of contact from the Lead IC. Evaluation and communications staff may also be included as necessary. To ensure multi-IC representation, the WG Co-Chairs can, if necessary, contact all IC Directors to invite nominations for WG membership. WG members participate on Project Teams for specific initiatives, review and edit draft FOAs, attend reviews, participate in the development of funding plans, and, where appropriate, serve as Project Scientists for cooperative agreements. WG Co-Chairs are responsible for providing overall guidance to the CF program and approving important programmatic products before they come to the OSC for review.

2) Findings

Comments from the survey and interviews with OSC staff and WG members were reviewed to assess the WG structure of CF programs. Survey participants expressed quite positive views about the WG structure. A very large majority of respondents agreed that the current structure is effective in meeting the scientific goals of the program (agree: 75%, neutral: 19%, disagree: 6%). Similarly, a sizeable majority felt that the current structure is effective for managing CF programs (agree: 70%, neutral: 20%, disagree: 10%). Respondents were mixed on whether OSC guidance on forming WGs was sufficient (agree: 38%, neutral: 39%, disagree: 23%). Responses were also mixed on whether respondents felt the OSC policies and procedures for managing WGs are clear (agree: 36%, neutral: 31%, disagree: 33%). This mixed response to the two latter questions shows that these are areas that need better communication.

Specific comments from the survey indicated that the success of a WG could be attributed to strong leadership and excellent organization, and that being part of WGs had been rewarding. Some respondents felt that efficacy of WG structures varied according to a number of different factors. In some cases participants felt that variability in WG structure diminished efficiency. Moreover, if members were not engaged in the program, or were not effective communicators, problems could ensue. Finally, a few respondents were confused about WG structure.

VIII. Are the roles and responsibilities of Working Group members clear?

1) Background

The success of a CF project hinges almost entirely on a highly functional and cohesive WG. A set of well-defined individual roles and responsibilities is key to a productive WG, because clearly articulated roles establish the skill sets required for WG members, set out expectations, and eliminate overlap for specific roles. Much of this information is contained within the CF Handbook.

From a program management perspective, CF projects are very different from typical IC-driven initiatives, and the roles and responsibilities of WG members reflect this. Among the challenges group members face are (1) communicating and coordinating CF activities across a number of ICs; (2) fostering collaboration among the PIs on the CF grants; (3) establishing goals and milestones and tracking progress for multiple PIs; and (4) responding to changes in the external scientific landscape. WGs generally comprise members from different ICs, and this requires members to reconcile the various practices and approaches inherent to each IC. Given the complexities associated with CF programs, it is not surprising that WG members found CF projects to be quite challenging to manage, but the same members also expressed a great deal of personal satisfaction in serving on CF WGs.

2) Findings

The CFEWG reviewed the CF Handbook section on Working Groups and Roles as well as interview and survey results to assess the clarity of WG roles and responsibilities. The publication of the CF Handbook in 2009 appears to have had an impact on the overall understanding of roles and responsibilities of WG members; the majority of respondents made positive responses to Question VIII, "*...the roles and responsibilities of Working Group members are clear*" (agree: 61%, neutral: 23%, disagree: 16%). Similar responses were obtained in the interviews conducted with IC Directors and WG members - it is apparent that the WG model for CF program management has been widely disseminated and understood. However, improvement is still needed. The CF Handbook, while distributed internally to the IC WG members and OSC staff, has not been read (or understood) by all WG members, and they ask questions of the OSC staff even though the answers are in the CF Handbook. Written feedback from the survey indicates that "*Some are confused as to who does what*," and "*I don't think expectations are laid out very well in the beginning*." In addition, the CF Handbook has not been distributed to the PIs on CF programs, and thus many of the roles, responsibilities, and best practices discussed in the CF Handbook are not transparent to PIs.

One important piece of feedback from our interviews with WG members is that they rarely interact with WG members from other CF programs. During a WG interview session with a group of between eight and ten WG members, one participant remarked that this had been the only forum for discussing CF WG best practices he had ever attended. WG members mentioned that OSC held monthly "All Hands Meetings," but that these meetings were not widely attended due to the perception that they did not add value.

IX. Is the value of the program worth the effort?

1) Background

"Value" can take on many different meanings depending upon the audience. For IC Directors, the value of CF programs is related to scientific impact; for individual ICs, value arises out of the trans-NIH interactions that are a key tenet of the CF; and for WG members, CF programs offer a

unique opportunity to work on a large, high-profile project with colleagues from many different ICs.

2) Findings

The CFEWG reviewed the CF Handbook section on Working Group and Roles as well as interview and survey results to assess the perception of the value of CF programs relative to the effort they demand. Feedback on this topic from the 2014 survey touched on a number of themes. In general, the respondents expressed very positive views about the overarching goals of the CF program, and felt that CF projects addressed areas of science that could not be tackled by an individual IC. In addition, nearly all survey respondents agreed that "*...the scientific mission of individual ICs benefits from working with other ICs on grants/projects*" (agree: 91%, neutral: 7%, disagree: 2%). The overwhelmingly positive response to this question suggests that working trans-NIH (a key aspect of the CF) is highly valued by NIH staff. Over three-fourths of survey respondents agreed that "*...collaborative work via the Common Fund involving multiple ICs is an effective use of NIH resources*" (agree: 80%, neutral: 15%, disagree: 6%). A majority of participants agreed that "*...Common Fund programs have increased the likelihood of collaborative, high-impact trans-NIH programs and activities*" (agree: 74%, neutral: 18%, disagree: 8%), and that "*...the Common Fund encourages a culture of change, shared resources, cooperation, and collaboration among ICs*" (agree: 60%, neutral: 26%, disagree: 14%).

These very positive responses are tempered somewhat by the responses to two follow-up questions. A majority of respondents agreed that "*...since the Roadmap/Common Fund began, ICs are more willing to work together on additional CF grants/projects than they were in the past*" (agree: 54%, neutral: 26%, disagree: 20%). Many respondents were unsure about the following statement: "*...since the Roadmap/Common Fund began, ICs are more willing to work together on non-Common Fund related grants/projects than they were in the past*" (agree: 34%, neutral: 42%, disagree: 24%). Taken together, these responses suggest that ICs do a good job collaborating on CF activities, but then return to "business as usual" when assembling new grants and projects. It should also be noted, though, that the responses to these two questions are more positive in 2014 than in 2005, indicating that momentum is shifting in a positive direction.

Overall, the CF is viewed positively throughout the NIH, and a comparison of responses from the 2005 and 2014 surveys shows that views have become more positive. In our interviews with IC Directors, nearly all Directors expressed a positive opinion of the CF. This was also true of our interviews with CF WG members. This is not to suggest that there are not aspects of the CF that should be changed - the survey and interviews captured many candid and critical comments. However, assuming that the recommendations contained in this report are implemented, CF programs should continue.

X. Do IC Directors get appropriate amounts of information about CF programs and at an appropriate frequency?

1) Background

The CF Handbook section on Communicating about CF Programs was reviewed to assess whether IC Directors receive appropriate amounts of information about CF programs. As described in the CF Handbook, OSC is responsible for collecting, disseminating, and reporting information about CF projects to a wide audience, including internal (NIH) scientists - a group that includes IC Directors. The mechanisms for getting information to IC Directors is not spelled out specifically; nor did a consensus emerge from our interviews with IC Directors and OSC staff. Furthermore, as we found in our interviews, IC Directors are a heterogeneous group, and thus the definition of "appropriate amounts" of information varies widely.

2) Findings

Comments from the 2014 survey and interviews with OSC staff and IC Directors were reviewed for information about communication. Regarding what constitutes an "appropriate amount" of information on CF programs, there appear to be two main drivers: (1) the amount of overlap between a given CF program and the research interests of the Director's IC; and (2) the level of buy-in that an IC Director has for the CF concept itself. Directors of smaller ICs tended to be more supportive of CF programs, while directors of larger ICs were generally less supportive.

The first issue is dependent upon conditions that will change over time; as CF programs come and go, new CF programs may emerge that overlap strongly with an IC's research interests. Interviews showed that IC Directors who are either leading or heavily involved in a CF program closely monitor the progress of the program against its milestones, and receive detailed monthly (if not weekly) updates from the CF WG. For CF programs where a given IC is not directly involved, the consensus feedback from the IC Directors is that they receive almost no information. Some directors mentioned that there used to be time set aside during the IC Directors' meeting with the NIH Director for CF program updates, but these updates stopped "*a few years ago.*"

The second issue is related, in part, to the process by which new CF programs are selected; many IC Directors reported feeling more detached from the decision-making process in recent years, and that prompted them to feel less enthusiasm for the CF in general.

Even if an IC Director wanted to obtain more information about a given CF program, finding and accessing this information does not appear to be straightforward.

XI. Does participation by IC staff on CF Working Groups enable efficient information exchange with IC Directors, IC Councils, other IC staff, and IC research communities?

1) Background

We reviewed the CF Handbook section on Communicating about Common Fund Programs to assess the efficiency of dissemination strategies for CF programs. By design, these programs cut across IC boundaries. Because of this, CF programs fall outside of the typical "intra-IC" flow of information, and this requires the members of a given IC to obtain information about CF programs via alternative sources.

2) Findings

As discussed during interviews with IC Directors, the IC Directors of ICs who participate directly in a given CF program felt that they were generally well-informed about that CF program, though this was not consistently the case for any of the other ongoing CF programs. IC Directors stated that they obtained this information through traditional "intra-IC" reporting relationships, rather than through the resources provided by OSC or other non-IC sources. The survey results suggest that many staff members within the ICs are not satisfied with the information they receive from senior management about the CF (satisfied: 46%, neutral: 20%, dissatisfied: 34%). These values are largely unchanged from 2005 (satisfied: 43%, neutral: 28%, dissatisfied: 29%). Comparing the responses to the 2014 survey by role provides some interesting insights: 47% of "highly involved" WG members, 41% of WG Coordinators, and 24% of Project Leaders expressed dissatisfaction. It appears that dissatisfaction increases with distance from senior management on the organizational chart, and this suggests that CF program information is flowing to senior management, but is not being effectively transmitted to the rest of the organization.

Recommendations for Management Processes

Recommendations for FOAs and Kick-off Meetings

RECOMMENDATION 22: ***Provide a comprehensive template for essential elements in CF program FOAs.*** OSC should develop a comprehensive template that specifies programmatic goals and milestones, defines the responsibilities of the PIs, and describes how the goals and milestones will be evaluated. The FOA template should be included in the CF Handbook.

RECOMMENDATION 23: ***Include GMOs early in the process of developing FOAs***. Early engagement of the GMOs will allow for their input and guidance.

RECOMMENDATION 24: ***Include information in the FOAs about how the CF is funded***. FOAs should include a paragraph noting that the CF has its own budget from the OD, and it is funded independently from appropriations to the ICs.

RECOMMENDATION 25: ***Provide links to relevant background documents in FOAs.*** FOAs should include links to relevant documents to help potential applicants understand the background of the specific CF program or field. The Epigenomics FOA could be used as an example.

RECOMMENDATION 26: ***State goals and milestones explicitly in FOAs and kick-off meetings.*** Explicitly state goals and milestones in FOAs, and reinforce them in kick-off meetings and documents.

RECOMMENDATION 27: ***A kick-off meeting for all new CF programs should be held with funded PIs, NIH staff, Steering Committee members, and external Scientific Advisory Committee members. The program's overall organization should be described in the CF Handbook to inform participants about the program.*** Both the kick-off meetings and CF documents should clearly lay out the goals and respective responsibilities of the PIs and NIH staff. The kick-off event and documents should also include identification of the membership of Steering Committees and the external Scientific Advisory Committees. Additionally, they should define expectations regarding interactions among investigators, specify the type of scientific interaction that will occur within the program, and outline the management and evaluation processes. All meeting events, documents, and provisions for management, evaluation, and oversight should reinforce the CF's transformative aspirations, endorse collaboration among the PIs, and include plans for dissemination of the work. The CF Handbook should include a section on expectations for kick-off meetings and documents.

Recommendations for CF WGs and OSC Program Directors

RECOMMENDATION 28: ***OSC Program Directors should educate WGs about the need for and use of Annual Progress Reports.*** OSC Program Directors should discuss the nature, structure, impact, and use of the Annual Progress Report with CF WGs. This discussion should highlight that annual reports provide important information for OSC. The report should be used as a means of validating and ensuring continued funding and/or making recommendations for changes to management, planning, and funding.

RECOMMENDATION 29: ***The CF WGs should review goals and milestones at least annually.*** Require the CF Program ESPs and PIs to review goals and milestones annually as part of the ESP review and address this in their annual progress reports submitted to NIH. External advisors should be identified when the CF program is launched. Selections for ESP membership should consider conflicts of interest

RECOMMENDATION 30: ***Define the working relationships and interactions between OSC Program Directors and CF WGs.*** Define procedures for OSC Program Directors regarding their working relationships and interactions with both IC program staff and IC Directors. The OSC Program Director is the critical link between OSC and WGs, and needs to be fully engaged to effectively facilitate clear and uniform management and communication.

RECOMMENDATION 31: ***OSC should improve guidance on forming WGs.*** WGs should include an experienced CF WG member from a successful program to ensure future success. Additionally, WG members should be drawn from multiple ICs. The group should include an appropriate number of members, not so large as to be cumbersome, but large enough to complete the work. There should also be clear procedures for adding and removing WG members.

RECOMMENDATION 32: ***Establish clear mechanisms for communications between CF PIs and their respective WGs.*** We recommend that all CF Program WGs have Steering Committees comprising PIs and NIH staff that meet regularly to manage the scientific direction of the program.

RECOMMENDATION 33: ***Encourage all WG members to use the CF Handbook as a guide for program management.*** The publication of the CF Handbook was a major step forward in establishing common management practices and defining key roles and responsibilities for all CF programs. We strongly recommend that the CF Handbook be updated regularly and distributed to all CF WG members.

RECOMMENDATION 34: ***Provide an orientation on WG structure for new CF programs.*** When new CF programs are initiated, we recommend that a one- to two-day "new WG startup" course be taught by experienced WG members, using the CF Handbook as a key resource.

RECOMMENDATION 35: ***Gather and disseminate CF "best practices" for the benefit of all WGs***. We also recommend that a monthly or quarterly CF "best practices forum" be established so that CF WG members can highlight key events in their CF programs and exchange best practices in managing the programs. Best practices captured during the forum should be included in updated versions of the CF Handbook.

RECOMMENDATION 36: ***Identify CF mentors who have successfully managed CF programs to guide new CF WGs***. New CF WG members should identify experienced mentors to serve as a key resource; this may happen organically at the CF "best practices forum."

RECOMMENDATION 37: ***Provide a CF Handbook to grantee PIs to inform them of CF program planning and management, or a version focused on information relevant to the PIs.*** The CF Handbook (or a modified version) should be shared with the CF PIs. While some information in the CF Handbook may not be appropriate or germane for CF PIs, the document offers explanations of organizational structures, abbreviations, timelines, and roles and

responsibilities. It is difficult to imagine that a CF PI would not benefit from receiving this information.

Recommendations for Evaluation of CF Programs

RECOMMENDATION 38: ***Clearly define evaluation plans at the outset of CF programs.*** OSC Program staff should make clear how each CF program will be evaluated at the outset of the program. In the interviews, WG members reported that they were unclear about the methods to evaluate the CF programs.

RECOMMENDATION 39: ***Conduct evaluation reviews prior to the end of the first phase of a CF program.*** Programs are funded for five years, referred to as phase 1 of the program, and then the decision is made on whether or not to proceed to a phase 2. OSC should ensure that this review includes information not only on progress made toward goals, but also a review of the transition plan for the program. Although the review can take place internally, an external review might be warranted in some cases. OSC should establish metrics and milestones for each program that, if not met, might trigger an external review.

RECOMMENDATION 40: ***OSC should conduct annual CF program management reviews to provide feedback to WGs on management of the CF program and whether the goals and milestones are being achieved.*** OSC should evaluate WG management and leadership of CF programs to determine whether it serves the goals of the CF program. This should include streamlining the OSC's management of WGs.

Recommendation for Intramural-only CF Programs

RECOMMENDATION 41: ***Justify the need for intramural-only CF programs, and establish clear processes for all aspects of intramural-only CF program management.*** A defined process comparable to that applied to extramural CF programs is needed to ensure validation of the programs, broad IC participation, and an enhanced likelihood of success in meeting program milestones. Management and oversight should be more structured and transparent.

Recommendations for Communication and Input

RECOMMENDATION 42: ***Explore ways to leverage the benefit of trans-NIH cooperative relationships developed through CF WGs to improve interaction between ICs on non-CF projects.*** Many of the trans-NIH relationships established on CF programs could benefit other non-CF programs.

RECOMMENDATION 43: ***Establish incentives to drive even greater participation and engagement in CF programs by IC Directors and staff across the NIH.*** These incentives could include compensation time, reduced workload, and opportunities for career and professional advancement.

RECOMMENDATION 44: ***Provide regular updates on CF programs to IC Directors: for example, quarterly updates at the IC Directors' meeting.*** Many IC Directors expressed a desire to receive high-level updates on all CF programs on an annual or semi-annual basis. Suggestions by IC Directors include a "CF Retreat" to receive high-level updates on all CF programs, and presentations about CF programs at IC Director's meetings.

RECOMMENDATION 45: ***Provide regular updates on CF programs to the NIH community***. We recommend that one of the first issues that the CF "best practices forum" should address is putting together a set of regular (e.g., quarterly) one-page updates of significant events that cover all CF programs in a uniform but concise format. These updates should be sent to all IC Directors and published on a website so that all NIH staff can access them.

RECOMMENDATION 46: ***Conduct a study to identify the best vehicle for communication about CF programs.*** Determine how best to directly provide information to NIH staff. The CF SharePoint operated by OSC was described in the written survey feedback as difficult to use. We recommend that OSC conduct usability studies with representative NIH staff to identify and resolve issues with the SharePoint, and solicit feedback from the "best practices" forum about other options/vehicles for communicating CF information more broadly.

RECOMMENDATION 47: ***Improve communication about CF programs by IC Directors.*** The survey results strongly suggest that the current methods for communicating CF information to NIH staff is not effective. The first problem to address is the lack of overall awareness among senior management (particularly IC Directors) about all CF programs; they seem to be well-connected to CF programs that they lead, or that involve the staff of their respective ICs, but as a group, IC Directors were very open about their lack of information on CF programs that did not overlap with their IC.

REFERENCES

Office of Strategic Coordination. *Common Fund Handbook*. 2009.

Department of Health and Human Services & National Institutes of Health. *Common Fund Strategic Planning Report 2013*. 2013. http://commonfund.nih.gov/sites/default/files/Rnd2a_2013_Strategic_Planning_Rept_NIH_0.pdf (accessed May 15, 2014).

National Institutes of Health & Department of Health and Human Services. *Common Fund Strategic Planning Report 2011*. 2011. http://commonfund.nih.gov/sites/default/files/CF_Strat_Plng_Rept_2011_Final_0.pdf (accessed May 15, 2014).

ORC Macro. *Design and Implementation of a Process Survey of the NIH Roadmap for Medical Research*. May 2005.

U.S. Congress. *National Institutes of Health Reform Act of 2006*. January 2006 (Act H.R. 6164). http://www.nih.gov/about/reauthorization/HR6164EnrolledVersion.pdf (accessed May 15, 2014).

APPENDICES