

## *Evaluation Response: NIH Council of Councils Common Fund Evaluation*

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### *Overview*

The first decade of the NIH Roadmap/Common Fund (CF) has produced over 30 programs and experimented with strategic planning processes to identify research topics and develop and manage programs. In September, 2013, the NIH Director established the Common Fund Evaluation Working Group (CFEWG) as a working group of the NIH Council of Councils (CoC) 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 it enters its second decade. The NIH asked the CFEWG to provide recommendations to be considered by the NIH Council of Councils at their meeting on June 20, 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 documents provided by the Office of Strategic Coordination (OSC) and results of surveys conducted in 2005 and in 2014. The CFEWG also conducted interviews with IC Directors, OSC staff, CF Program Working Group members, Grants Management Officers, Budget Points of Contact, Executive Officers, Planning and Evaluation Officers, and members of the Extramural Program Management Committee. It delivered 47 recommendations in a report dated June 19, 2014. This report was discussed and approved by the CoC and transmitted to the NIH Director who accepted the Council's recommendations on July 7, 2014.

The OSC engaged IC staff to help develop this Response, which addresses CF planning and management in separate sections. The recommendations included cross-cutting themes of enhanced communication and transparency in decision making and expanded opportunities for engagement by IC Directors and by the CoC. Responses to these cross-cutting themes are addressed in each section. A full list of the Council of Councils' 47 recommendations can be found as Appendix to this document. Many

recommendations are similar and can be summarized as addressing a smaller list of issues. Consequently we will provide responses to groups of similar recommendations and not to each individual recommendation. Input from the IC Directors, provided at the October 2014 NIH Leadership Forum, in reaction to the recommendations was also incorporated in developing these responses.

### *Strategic Planning (Recommendations 1-21)*

CF strategic planning is a multi-phase, iterative process through which challenges are identified and opportunities for transformative impact within a 5-10 year time frame are considered. Phase 1 planning involves the consideration of many ideas for new CF programs and the development of a “rough draft” set of initiatives that might form the program. This phase ends with a decision by the NIH Director to pursue further planning or to remove the idea from further consideration. Phase 2 planning then involves the creation of a trans-NIH team that analyzes relevant ongoing, NIH-wide research and that engages external or NIH intramural scientists to help articulate specific goals for the program. This phase ends with a decision by the NIH Director to support the program, to reconsider it after additional planning is conducted, or to not support the program.

The CFEWG recommendations for Strategic Planning can be summarized as follows:

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

Response plans for each of these is provided below.

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

A number of strategies have been employed to gather input from diverse NIH stakeholders, including conducting a series of meetings involving invited thought-leaders, conducting open regional meetings, issuing Requests for Information via the NIH Guide, soliciting input online via social media sites, and asking for input from IC Directors, who collectively represent the NIH community at large. The central lesson learned to date from these efforts is that the articulation of concepts that meet expectations for the Common Fund – “Common Fund’able concepts” – requires iterative discussion. The breadth of the science that could potentially be supported via the Common Fund makes the identification and specification of new programs challenging: programs must not only address broadly relevant challenges, they must articulate specific goals and deliverables to have a transformative, catalytic impact on the field within a 5-10 year timeframe.

OSC Response:

- ✓ In Phase 1 planning, OSC will use a variety of approaches to gather input from NIH stakeholders, tailoring the planning activities each year in anticipation of funds available. Meetings of external scientists and broad solicitation of input via social media or RFIs will occur approximately

biannually. In addition to local meetings, OSC will begin to take greater advantage of national conferences to meet with stakeholders and brainstorm about potential new program areas and enhancement of existing CF programs. In the years when this type of broad outreach is not undertaken, concepts for new programs will be solicited from IC Directors if funds are expected to be available. OSC Program Leaders and OSC/DPCPSI Leadership will be active participants in meetings with external scientists and in discussions with NIH staff to facilitate the formulation of concepts that meet the expectations for Common Fund concepts.

- ✓ As described below, the IC Directors will be engaged prior to concept clearance by the CoC to help shape new concepts. This will help to ensure that concepts that are considered by the Council are of broad interest and priorities for the ICs and have sufficient detail to allow an informed discussion by the Council.
- ✓ The Council discussion provides additional broad perspectives to be brought to bear on the early development of the program.
- ✓ In Phase 2 planning and during planning for a second phase of support for existing programs, Working Groups will conduct outreach to external and intramural scientists as appropriate for the particular scientific area. Investigators who are working in the field will be invited to articulate the current status of the field and to identify challenges and opportunities. Potential users of the data/resources/etc. that the program would develop will also be engaged. Attempts will also be made to engage potential skeptics of the program.

Clarify the criteria for new CF programs, including those which address urgent needs and those that involve allocation of funds to intramural investigators.

Despite attempts to clarify and operationalize the CF criteria for new programs, interpretation of these criteria is inevitably subjective. Iterative discussion is required to clarify the criteria with any group or individual who is considering new concepts. Programs that address urgent needs should meet the same criteria; the timeline for implementation of these programs is compressed but should otherwise be identical to other programs. Programs that involve allocation of funds to intramural investigators without competition with extramural investigators also must meet these criteria.

OSC Response:

- ✓ During the earliest phases of articulating concepts and during planning for a second phase of support for existing programs, OSC staff will be available to meet with NIH staff and external scientists to help define the Common Fund criteria. OSC staffing will be adjusted to allow more time for these discussions in Phase 2 as well, with the expectation that OSC will be a full partner with lead ICs as goals for new programs are established.
- ✓ A small group of IC Directors will be engaged both before a concept goes to the Council for clearance and during Phase 2 planning. These small groups will be composed of volunteers who express a willingness and interest in participating in planning at a higher than typical level. Their discussions will help to clarify criteria for new programs with the Working Groups and will ensure that the program proposals are broadly relevant.
- ✓ The decision to pursue a given set of goals via intramural-only funding will be made as part of Phase 2 planning. The decision to implement a given set of goals via intramural-only funding is a strategy decision, while Phase 1 planning addresses the goals themselves. This distinction will be made clear in all calls for concepts. Council review of Phase 1 concepts will focus on the scientific goals to be achieved. Review of specific strategies to achieve the scientific goals will be conducted by DPCPSI, a small group of IC Directors, the NIH Principal Deputy Director, and the NIH Director at the end of Phase 2 planning. The criteria for considering allocation of funds to the intramural program without competition which were established by the NIH Steering

Committee will be shared with all CF Working Groups as Phase 2 planning proceeds (see Appendix B).

Provide opportunities for richer participation by the IC Directors and the CoC as concepts are developed and selected

Collectively through several recommendations, the Council of Councils recommended that NIH reconsider the processes through which IC Directors provide input on goals and priorities for potential new and continuing programs. This reflects a strong endorsement of the idea that the CF should focus its programs on shared priorities.

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

OSC Response:

- ✓ OSC will engage IC Directors in program planning and decision making in two ways: 1) In regularly scheduled meetings of the IC Directors, DPCPSI will lead high level discussion of funds available, planning processes, and concepts being considered. This will allow the entire group of IC Directors to be kept apprised of CF programs and assess the general sense of enthusiasm or concern. 2) Detailed discussions will be held as concepts or programs face a major decision point. All IC Directors will be invited to participate, but those with a particular interest in the issue may be the most likely to dedicate time to these discussions. OSC will schedule these discussions as far ahead as possible to enable greater participation by the IC Directors. Questions that will be considered in this type of discussion include: Is a given concept ready to be discussed/cleared by the Council of Councils? Is a given Phase 2 proposal ready for discussion with the NIH Director? How might it be adjusted? What is the appropriate size and scope compared to other CF priorities? As ongoing programs develop plans for a second stage of support, are the plans likely to create the need for long term, dedicated funds from the ICs? How should the second stage of CF support address the long term support of the science?
- ✓ Greater participation by the IC Directors in the early stages of concept development will allow concepts to be more fully formed when they are sent to the Council of Councils for concept clearance discussion. This is expected to result in fewer concepts being provided to the Council. This will therefore allow a richer discussion of each concept during the clearance process. Concepts will include a rough estimate of size and scope, and each will be discussed with the Council. After a concept has been cleared and Phase 2 planning is underway, it will be reviewed with the Council at a subsequent meeting with further input helping to shape the final program plan.

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

The call for enhanced partnership between OSC and the ICs by the CFEWG was accompanied by a recommendation that OSC be given the resources to devote more staff effort to the planning and management processes. This recommendation will allow OSC to do the following to increase transparency and communication with IC colleagues:

- ✓ Meet in small and large group settings with IC staff to discuss CF criteria, processes, and plans for managing programs.
- ✓ Engage in fluid dialog with IC colleagues as concepts are planned and managed

- ✓ Devote dedicated staff time to orchestrate portfolio analyses with Working Groups to ensure consistency and to ensure that program-specific questions are addressed.
- ✓ Support orientation and team building activities with Working Group coordinators to promote idea sharing and partnership as new groups are established.

### *Program Management (Recommendations 22-47)*

The short term, goal driven, and trans-NIH nature of CF programs sets them apart from IC-supported science and requires a different approach to management. Utility of the program's deliverables to the broader community is a prime measure of a program's success. In recognition of the differences between CF programs and IC programs that aim to stimulate or support a given field for long term growth, the CFEWG made recommendations for Program Management that can be summarized as follows:

- Work fluidly with CF Working Groups to develop a common understanding of goals, milestones, and program management plans.
- Communicate in diverse ways to ensure general familiarity with the CF and to ensure that grantees, NIH staff, and end-users are aware of goals and deliverables.
- Ensure that evaluation plans are developed early in the life of the program; ensure that grantees are fully familiar with the end goals for the program and with plans to assess the program throughout the life of each award.
- Engage the IC Directors throughout the life of the programs.

Response plans are described below.

#### Work fluidly with CF Working Groups to ensure a common understanding of goals, milestones, and program management plans

Enhancing communication and interaction with IC colleagues will be a major emphasis for OSC moving forward. An online document that details CF operating procedures, known as the CF Handbook, will be updated and expanded upon to provide best practices when possible, the unique features of each program demand dedicated discussions to ensure that the implementation and management plans are appropriate.

- ✓ OSC staff and experienced IC program staff will provide an orientation to new Working Groups, describing several best practices in the CF Handbook and covering expectations for working together.
- ✓ OSC and IC program staff will work in partnership to develop a program management plan that anticipates flexibility each year to adapt in response to changing scientific issues.
- ✓ The annual program review and operating budget planning process will be an interactive, bi-directional activity, with OSC Program Leaders providing annual budget information and the team working together to develop a strategy for the coming year.
- ✓ OSC Program Leaders will work closely with IC coordinators who have less experience with CF programs to relay experiences and lessons learned.
- ✓ Memoranda of Understanding will be developed with all intramural-only programs and initiatives to ensure a common understanding of goals, deliverables, and oversight mechanisms. The oversight mechanisms will be tailored to the specific goals of the program but will adhere to

the principles of Common Fund management generally that ensure utility of the program to the community at large.

Communicate in diverse ways to ensure general familiarity with the CF and to ensure that grantees, NIH staff, and end-users are aware of goals and deliverables and CF processes.

The CFEWG report indicated a general lack of awareness of CF programs in the external community and among NIH staff. Increasing awareness is important not only to ensure robust participation by the scientific community in each program but also to ensure that the deliverables from each program have maximum impact. Ensuring that program staff members across the NIH are aware of these programs will help to ensure that grantee communities also become aware of the tools, data, and other deliverables.

- ✓ In addition to communications and outreach strategies for each individual program, OSC will develop and implement an outreach strategy for the CF as a whole. This will include provision of information at national and international conferences, professional society meetings, or other venues where relevant audiences are present.
- ✓ The outreach strategy for individual programs will target relevant investigator communities to provide information about deliverables from the program and to foster uptake and use. A variety of approaches will be used to disseminate information to users, including presentations at conferences, use of social media group sites, linking to relevant blogs and community newsletters, and other communications approaches that may be identified.
- ✓ OSC will begin a seminar series highlighting CF program accomplishments and deliverables to help ensure that NIH extramural program directors are aware of the utility of these programs for their communities. To maximize the value of these seminars, they will be held in conjunction with Council of Councils meetings and will therefore serve the purpose of updating Council members as well.
- ✓ Slide sets and other communications materials will be shared across the NIH, including with IC Directors, to help ensure broad dissemination.
- ✓ CF-funded PIs and IC program staff will be able to review descriptions of CF processes via the CF Handbook.

Ensure that evaluation plans are developed early in the life of the program; ensure that grantees are fully familiar with the end goals for the program and with plans to assess the program throughout the life of each award.

Since many NIH programs are not formally assessed with respect to achievement of defined goals and transformative impact, NIH program officers and scientists who receive grants are often unaccustomed to establishing and implementing plans for evaluation. OSC plays a significant role in bringing these discussions to the table, and in response to the CFEWG, this role for the office will be clarified, with increased attention paid to the development of evaluation plans very early in the program's implementation.

- ✓ Phase 2 strategic planning should articulate clear goals and deliverables, with an expected timeline of intermediate milestones established. These goals and timelines often require iterative discussion through the Funding Opportunity Announcement (FOA) development and award issuance processes. OSC Program Leaders and IC Coordinators for each program will work closely together during this iterative process to establish clear goals and expectations for the program, each initiative, and each award.

- ✓ While the FOA for each initiative should articulate the goals of the program as a whole and of each initiative, the Notice of Grant Award (NGA) must clearly state specific expectations for each award. OSC and IC staff will work closely together to negotiate milestones for individual awards and to provide input to Grants Management on Terms and Conditions that will provide NIH with appropriate flexibility to manage each award. These documents serve as primary communication to Principal Investigators with respect to NIH expectations for their award.
- ✓ Kickoff meetings and annual grantees' meetings will become standard for CF programs to ensure that grantees are fully aware of NIH expectations for the program and to keep the expectations aligned with the science as new knowledge is acquired. These meetings also allow an impartial External Scientific Panel to both participate in the grantees' meeting and meet separately to assess the program's progress. This assessment will help ensure that the programs are working toward outcomes that will have a transformative impact for a broad community.
- ✓ A critical stage for program assessment will be approximately two years before funding is scheduled to end. At this phase, OSC and the WG will assess the accomplishments and impact of the program, with emphasis on the user community: who has benefited from the program's deliverables and how? This assessment will include discussions with IC Directors and with the Council of Councils as time permits, so that these groups can provide input about the need for continued CF support. The assessments will then inform decisions about a second stage of CF support for programs ending their first stage of support, and it will inform decisions about the need for continued set-aside funding (if any) by the ICs for programs that are nearing the 10<sup>th</sup> year anniversary of CF support.

Engage the IC Directors throughout the life of the programs.

The plans described above provide opportunities for richer discussion of CF programs by IC Directors during the planning stages for new or continuing programs, and it provides opportunities for substantive discussion of program accomplishments near the mid-point and/or closeout of each program or its transition from support by the CF. Time constraints preclude detailed briefings for IC Directors on each program on a more frequent basis. However, the annual progress reviews and operating plans for each program will be available to the IC Directors, and all IC Directors will be invited to hear about the accomplishments of CF programs at the quarterly CF seminar series. By providing more opportunities for DPCPSI/IC Director dialog, processes for engagement are expected to evolve as needed to ensure that the CF is managed in partnership.

## **Appendix A: The 47 recommendations of the CFEWG**

### **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.*

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.*

## *Appendix B: The Common Fund Criteria*

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 individual missions of NIH Institutes and Centers to benefit health
- Cross-cutting: Program areas must cut across missions of multiple NIH Institutes and Centers, 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