

COUNCIL OF COUNCILS OPERATING PROCEDURES

September 11, 2020

I. INTRODUCTION

The Council of Councils (Council) was authorized by the National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) “... for the purpose of advising the Director, NIH on matters relating to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), including making recommendations with respect to the conduct and support of research described in subsection (b)(7).” Subsection (b)(7) refers to research that is deserving of special emphasis and that would benefit from strategic coordination and planning. The Council is a standing advisory committee of the NIH and advises and makes recommendations to the Director, NIH, and the Director, DPCPSI. Sections of the NIH Reform Act that are relevant to the Council and DPCPSI are appended to these Operating Procedures.

The Council provides second-level review of:

- all grant and cooperative agreement applications assigned to the Office of Research Infrastructure Programs (ORIP);
- grant and cooperative agreement applications as appropriate to programmatic requirements and priorities for the Environmental influences on Child Health Outcomes (ECHO) program and the *All of Us*SM Research Program; and
- selected applications¹ for Common Fund (CF) support.

It also provides review of other requests for support for which Council recommendations are required by law. Further, the Council reviews and provides clearance for concepts for ORIP, CF, ECHO, ~~and~~ *All of Us* Research Program, and Lasker Clinical Research Scholars Program initiatives. Council members serve as a national resource that advise the NIH in the development and recommendation of DPCPSI policies and research priorities. On occasion, special working groups of the Council are formed to examine and address critical scientific or policy issues of importance to DPCPSI and the NIH.

II. REVIEW OF GRANT APPLICATIONS (Closed Session)

The Council conducts the official review of grant applications in a closed session of the Council meeting. Individuals with a real or apparent conflict of interest with an application must leave the meeting room for the duration of the discussion of the application.

A. Overview (Applicable to CF, ORIP, ECHO, and *All of Us* Research Program Applications as described in Section I).

The first level of the NIH peer review process, the scientific and technical review of applications, is the responsibility of the scientific review groups (SRG). Review by an Advisory Council or Board constitutes the “second level” of the two-tiered peer review process. The primary purpose

¹ Pioneer, New Innovator, Transformative Research, and Early Independence Award applications.

of the second level of review is for the Council to advise the Director, NIH, and the Director, DPCPSI, about the appropriateness of the initial review. In addition, the Council may make recommendations regarding the program balance of the CF and ORIP research portfolios, and the priority with which DPCPSI should attempt to support certain studies.

The Council may not change the numerical ratings (e.g., impact/priority score, percentile, criterion scores) resulting from the initial review, nor may it change the codes associated with animal welfare, the welfare of human subjects, or the representation of gender and/or minorities and/or children. However, the Council may recommend a change in the order of consideration of certain applications for funding, e.g., by designating an application as High Program Priority, thereby raising its priority for funding.

The Council's recommendations about which applications should be supported are advisory only and are not binding on DPCPSI or the NIH. The only specific, binding action that Council may take is to designate which application(s) should not receive support on the basis of scientific and technical merit, or other considerations. Such issues are discussed and decided by majority vote of the members appointed to the Council.

B. Special Issues Requiring Council Review

By NIH policy, before funding applications with special issues, they must be presented to, and recommendations obtained from, Council. Upon request, Council members will be provided access to individual ORIP, CF, ECHO, or *All of Us* Research Program grant applications that are reviewed under II. B.1-B.2, of these Operating Procedures.

1. Applications from Foreign Institutions

In reviewing and making recommendations on applications from foreign institutions, Council members should be aware that ALL of the following criteria must be met in order for a foreign grant to be supported by the NIH:

- a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
 - b. The project has specific relevance to the mission and objectives of DPCPSI and has the potential for significantly advancing the health sciences in the United States.
 - c. The application must be approved for funding by the Council.
 - d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.
2. Applications with Unresolved Concerns about Human or Animal Subjects; Inclusion of Women, Minorities, or Children in Clinical Studies; or Biosafety, Biocontainment, or Security of Select Agents

The Council is asked to comment on any application(s) proposed for funding with unresolved concerns in the areas in II. B. 2. above. The Council is asked for concurrence with the SRG's concern(s).

C. Letters of Appeal

The Council reviews ORIP appeal letters that were submitted by applicant institutions on behalf of the investigators subsequent to the peer review of their application that were not resolved by program and review staff. It is the responsibility of program staff, in consultation with review staff to determine whether a letter constitutes an appeal. The application will be made available via the Electronic Council Book (ECB) for Appeals on request. This section (II.C.) is not applicable to CF, ECHO, or *All of Us* Research Program applications because their FOAs do not permit submission of appeals. If a CF, ECHO, or *All of Us* Research Program FOA is issued that permits appeals, the guidelines outlined for ORIP applications apply.

An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered to be an appeal. Procedural issues fall under four categories, and the applicant must claim one or more of the following:

- a. The initial review was biased.
- b. A conflict of interest existed with at least one member of the SRG.
- c. The SRG lacked appropriate scientific expertise.
- d. Factual errors entered into the review.

Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

The Council has two options when reviewing an appeal letter: (1) The Council may concur with the applicant's appeal and recommend the application be re-reviewed, or (2) The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. If the Council concurs with the applicant's appeal, the re-review would be conducted by the same or a different review group depending on the flaws in the original review process that led to the appeal; this decision is made by NIH staff. The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

D. Council Communications

Other letters, termed Council Communications, are also made available to the Council at the discretion of ORIP, CF, ECHO, or *All of Us* Research Program staff. The issues identified in Council communications have been reviewed and resolved by program and/or review staff prior to the Council meeting. Thus, they are provided for information to, and do not require action on the part of, Council. Examples of such communications are a claim of a deficiency in the

scientific review of an application, or perceived lack of appropriate scientific expertise on the SRG, among others. These assertions are reviewed by program and review staff, a determination is made, and a summary provided of each Council communication and resolution.

E. Special Council Review of Pending ORIP Applications from Well-Funded Investigators

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has a policy of Special Council Review (SCR) of applications from well-funded investigators.² Pending ORIP grant applications to be reviewed by Council from Program Directors/Principal Investigators (PD/PI) who have more than \$1 million in direct costs from active NIH Research Project Grants (RPGs) grants will be subject to additional consideration. It is important to recognize that this is a threshold only; investigators who have more research support may still receive additional awards as warranted. When making funding recommendations, staff will take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award would affect other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

1. Criteria Considered by ORIP Staff for Determining Applications Subject to SCR:
 - a. Only funds acquired³ through RPGs⁴ should be included when calculating a given PD/PI's support.
 - b. Only competing RPGs (New and Renewals) to be considered for award to investigators with \$1.0M or more of direct cost NIH support are subject to SCR via this policy.
 - c. P01s and other Multi-Component RPGs:
 - i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have \$1.0M or more of NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
 - ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the \$1.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.
2. Multiple PD/PI Projects:
 - a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the \$1.0M threshold.

² SCR described in II.E. is not applicable to CF applications because they are solicited only via RFAs. Applications submitted in response to RFAs are excluded from SCR (see II.E.3.).

³ Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Year: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)

⁴ RPGs are defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

- b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.
3. Requests for Applications (RFAs):
 - a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the Institutes and Centers (IC) to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
 - b. Funds provided through these grants will contribute to the \$1.0M threshold for the investigators' future applications.
4. Competing Revisions and Administrative Supplements:
 - a. These types of awards are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the \$1.0M threshold. In order to prevent Re-entry and Diversity Supplements from being an impediment to an investigator, to the extent possible, these supplements should be excluded from the threshold count.
5. Guidelines for Council Consideration (Council role):
 - a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
 - b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
 - c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the \$1.0M direct cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

F. Common Fund, Environmental influences on Child Health Outcomes, and *All of Us* Research Program Application Review

Approximately 2 weeks before a Council meeting, the Council members receive access to an ECB containing the peer review results for grant applications as detailed in II.A. (above). The ECB materials include fact sheets/instructions, lists of all applications, summary statements, and any items that may be flagged for special discussion.

Council members are invited to identify applications they wish to raise for special discussion at the meeting. Such discussions could include the consideration of applications for high or low program priority, or deferral of an application based on unresolved issues.

Applications that are not specifically discussed by the Council are recommended by an *en bloc* vote for concurrence with the recommendations of the SRG.

G. Office of Research Infrastructure Program (ORIP) Application Review

1. Early Concurrence Review

In an effort to streamline Council review of Scientific Review Group recommendations and to expedite funding actions, ORIP/DPCPSI developed the following procedures:

- a. The Executive Secretary of the Council identifies applications that are eligible, i.e., those with scores of 40 or better, for the Early Concurrence review process, on behalf of the Council. Early concurrence review will not be used for any application described in section B.1 of these Operating Procedures, or:
 - i. Was identified by a Council member to be of special concern;
 - ii. posed any special policy issues;
 - iii. was previously deferred by Council for additional information or for re-review; or
 - iv. was identified by DPCPSI staff as requiring special consideration (e.g., high program priority, restoration of time or budget, etc.) or discussion by Council.
- b. The Executive Secretary selects at least two Council members to conduct the Early Concurrence review for each application.
 - i. The selected Council members will be provided with the list of grant numbers for those applications they are assigned to review. Summary statements will be available through the ECB.
 - ii. If an Early Concurrence-review assigned Council member determines an application should come to the full Council for discussion or should not be expedited for any reason, he/she needs to notify the Executive Secretary of this fact, and the application will be removed from the Early Concurrence consideration.
 - iii. Council members who were selected to perform Early Concurrence reviews will notify the Executive Secretary of the results of their review within a defined period of time. Those applications which receive positive Early Concurrence from the assigned reviewers (on behalf of the Council) are considered to be recommended for approval for funding and will not be voted on by the full Council.
 - iv. A report of the Early Concurrence recommendations will be posted to the ECB in advance of the Council meeting.

2. Applications Identified by Staff for Discussion

Staff may identify for consideration by Council those applications that they feel deserve specific discussion, such as applications that pose a special policy issue, where the summary statement includes a minority report from the SRG, when there is reason for staff to discuss some aspect of the SRG's recommendation, or when there are other programmatic concerns. The application summary statement will be posted to the ECB, a staff recommendation will be made, two Council members will be assigned to review the staff recommendation, and the full Council will be asked to vote on the staff's recommendation at the Council meeting. A quorum must be available either in-person or by telephone for the vote.

3. All Other ORIP Grant Applications

All applications that are not reviewed by the Early Concurrence review process or individually discussed by the Council are recommended by an *en bloc* vote for concurrence with the recommendations of the SRG. All members may participate in the *en bloc* vote since individual applications are not discussed. Alternatively, this review process could occur via teleconference.

III. ADVISORY ROLE OF THE COUNCIL OF COUNCILS IN PROGRAM PLANNING AND POLICY (Open Session)

An important role of the Council is to advise the NIH Director (through DPCPSI) on future plans and directions for scientific research. Council members review objectives, priorities, and accomplishments of DPCPSI's programs in terms of adequacy of funding, program management and administration, and responsiveness to public health needs. They also review concepts⁵ for potential Funding Opportunity Announcements (FOAs).⁶

The Council's involvement in matters of policy includes participating in discussions of NIH and DPCPSI policies and their implementation.

A. Concept Clearance

The Council reviews concepts for potential research initiatives in open session. These concepts originate in the scientific community, NIH, constituency organizations, and Congress. The purpose of concept clearance is to ensure that CF, ORIP, ECHO, ~~and~~ *All of Us* Research

⁵ Concept (NIH Glossary [<https://grants.nih.gov/grants/glossary.htm>]): The earliest planning stage of an initiative [Request for Applications (RFA) or Program Announcement (PA)]. Concepts are brought before the Advisory Council for concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds. Only concepts for RFAs, PARs, and PASs are reviewed by Council.

⁶ Funding Opportunity Announcements or FOAs are publicly available document that makes known the intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. FOAs are published as different announcements. Requests for Applications (RFAs) identify a narrowly defined area with set aside funds. Program Announcements (PAs) identify areas with increased priority or emphasis. PARs are PAs with special receipt, referral or review consideration; PASs are PAs with specific set-aside funds.

Program, and Lasker Clinical Research Scholars Program programmatic funding plans and priorities adequately address the objectives defined for these offices.

1. General Principles for Concept Reviews that may lead to Funding Opportunity Announcements (FOAs)

The NIH Office of Extramural Research sets NIH-wide policies for concept clearance which include the requirement for public discussion of new concepts. In the presentation of new concepts, the NIH must describe the purpose of the new initiative(s), its scope, objectives, and expected outcomes. Advisory Councils, or another comparable FACA committee consisting of Special Government Employees, discuss the proposed concepts and provide input about how the concepts may need to be adjusted. Each initiative must be cleared through this process before it can be implemented, and the clearance must be documented in the Council/FACA meeting minutes.

Council concept reviews for funding opportunities that are communicated through a Guide Notice or Notice of Special Interest (NOSI) under an existing FOA only apply to Guide Notices or NOSIs that have specific set aside funds identified for the intended purpose.

Whenever possible, Council review of concepts will be grouped by Program Office. For each concept under review, program staff will inform Council if the concept is a reissue of a FOA in support of an existing program or a new concept for an initiative leading to a new program.

- 1.1. For reissuance of FOAs,⁷ program staff will provide a short introduction regarding the program funded by the FOA, describe how the program/FOA supports the NIH and individual office missions, identify potential program/FOA highlights, accomplishments, or, if possible, other metrics that demonstrate impact of the program/FOA to date, and, describe the need for the continuation of the program (including a summary of both affirming and dissenting opinions).
- 1.2. For new concepts,⁸ which are developed over time with input from workshops and meetings, program staff will provide more general background covering both affirming and dissenting opinions, that will help Council appreciate the innovative, cross-cutting, transforming, catalytic, or unique aspect of the new initiative leading to a new program and how it will support and synergize with the overall NIH and individual office missions.

For each concept, the following components may be used as parts of the Council clearance process: written materials provided by program staff in advance for Council to review, a brief oral presentation by program staff during the open session of the Council meeting covering the pertinent aspects of the program or initiative, and the assignment of two Council members who

⁷ Reissuance: Reissuance refers to a concept for a FOA that has been previously published, or one that has received prior funding and is being considered for continued support for another funding cycle with minimal changes. Reasons to reissue a concept can include renewal of a previously established program or initiative or to provide additional opportunities for the research community to respond to the program goals.

⁸ New Concept: New refers to a concept for potential FOA not previously proposed, or one that has not received prior funding.

will make oral comments during the open session of the Council meeting. During the open Council session, each concept will undergo a discussion and vote.

2. Common Fund (CF)

Each CF program addresses cross-cutting needs or opportunities that require multi-IC coordination and strategic planning. These programs are implemented through one or more strategically linked initiatives, each of which is intended to address objectives that contribute to the overarching goals of the program. At the outset of a new program, or at a point when it is being considered for a second phase of support, the Council will review the concept for the program as a whole as well as for the individual initiatives that are proposed. The review of the concept for the entire program addresses the question of whether the program aligns with the criteria for Common Fund programs. The review of each initiative addresses the question of whether the initiative is a critical component of the strategy to achieve the goals of the whole program. Council may vote to clear the program as a whole or may vote separately on individual initiatives.

The concept clearance process also involves consideration of the estimated costs to achieve the goals of the program as a whole and the goals of individual initiatives. Common Fund programs typically represent substantial investments in a given scientific arena; while the budgets for each initiative may change during the implementation phase, Council input helps ensure that individual initiatives are appropriately supported to achieve the programmatic goals.

As Common Fund programs are implemented, it may become necessary to add new initiatives that address emergent needs or opportunities within a given program area. In these cases, concepts for single FOAs will be presented for concept clearance.

Presentation of concepts includes provision of written documents approximately two weeks in advance of the Council meeting. Two Council members will be asked to serve as discussants and will provide opening comments and initial recommendations. The Council, by a simple majority vote of the appointed members, will recommend approval, modification, deferral, or disapproval of a program concept as a whole or the concept's individual initiatives. A vote to approve is to accept the concept/initiative as written and presented. A vote to modify is to approve the concept/initiative with clearly stated modifications; if modifications are made, the concept/initiative would not need to be brought back to Council for approval. A vote to defer is a vote to call for additional information and/or external input to re-shape the concept/initiative or to clarify the need. In these cases, the revised concept/initiative must be discussed and cleared at a future Council meeting. A vote to disapprove reflects Council opinion that the goals of the initiative or program should not be pursued with Common Fund support.

3. Office of Research Infrastructure Programs (ORIP), ECHO Program Office, ~~and~~ *All of Us* Research Program Office, ~~and~~ *Lasker Clinical Research Scholars Program*

ORIP, ECHO, ~~and~~ *All of Us* Research Program, ~~and~~ *Lasker Clinical Research Program* staff prepare concept presentations for review by the Council. Written materials will be made available to all Council members approximately two weeks prior to the Council meeting. Two

Council members will be assigned as reviewers; they will comment on the program or initiative and make a recommendation. The Council will be asked to vote and to recommend approval, modification, deferral, or disapproval of a concept. Approved concepts are the basis for programs initiated through FOAs, although there is no guarantee if the Council approves a concept that it will be developed into a FOA. In the event that a concept is judged by the Council to be unlikely to achieve the stated goals for the initiative or to be inconsistent with the goals for the program as a whole, the Council may describe changes that could be incorporated to make the initiative acceptable. The concept would not require re-review if these changes were later incorporated. If an existing program presented for reissue/renewal is judged by the Council to have failed to achieve the stated goals for the program or to be inconsistent with the goals and mission of the NIH and individual office, the Council will outline what information is missing or what additional information would be needed for the Council to consider approving the concept for the reissue.

IV. AUTHORITIES DELEGATED TO STAFF

On a yearly basis, the Council delegates to DPCPSI some actions that are normally the responsibility of the Council. In accordance with stated policies of the Public Health Service (PHS) and the NIH, and with the concurrence of Council, the staff of the Office of the Director, NIH, may use administrative discretion to:

- A. Take administrative actions as allowed by applicable U.S. Department of Health and Human Services (DHHS), PHS, and/or NIH policies and procedures. Note: for Common Fund awards, administrative management is provided by Institutes and Centers; these decisions, as well as the actions below, are therefore guided by the relevant IC Council operating procedures.
- B. Provide limited interim funding when a recommendation of deferral on a competing continuation application would result in a loss of continuity of the project.
- C. Provide additional funds to a noncompeting application when well justified and when NIH resources allow; for example, institution-wide salary and fringe benefit increases, and increased costs of supplies. These and other increases of an administrative nature may be provided, if not related to an expansion of the scope of the project or to a significant change in scientific direction.

Council review is required for additional funds to ORIP grants in the following situation:

- 1. Additional funds that qualify under the above criteria (e.g., within the scientific scope of the original award), if the additional funds are:
 - a. in excess of \$500,000.00 of total costs, or
 - b. greater than 50% of the direct costs of the parent award.
- 2. If it is determined that Council should review such a case, ORIP staff will prepare a summary of the award's circumstances requiring the proposed additional funds, any

accompanying documentation, and the original application's summary statement. Two Council members will be assigned to review the staff recommendation and the full Council will be asked to vote on the staff's recommendation at the Council meeting. Action will be taken after a majority of the Council members voted on the recommendation.

3. Under the 2020 coronavirus pandemic emergency causing COVID-19, the Council delegates to DPCPSI actions to provide additional funds to noncompeting applications when well justified and when DPCPSI or other NIH resources are available.
Consistent with NIH policy, in cases where appropriate justification is provided and approved by NIH officials, the cumulative amount of an administrative supplement may exceed the parent award.
- D. Provide support to restore direct costs and/or years deleted in initial review of competitive applications in amounts to meet the needs of the project and priorities of DPCPSI. Council recommendations, program policy, and relevance and resources will serve as guides in making such adjustments.
- E. Provide for additional slots on institutional training grants to deal with unusual situations or unexpected opportunities.
- F. Provide for orderly termination or continuation of support in order to prevent loss of research material or hardship to personnel by awarding an administrative supplement, a grant, or a cooperative agreement, not to exceed one year and in an amount not to exceed a prorated level of current support when an application has not been recommended for funding or has been recommended for deferral.
- G. In the event of a federally declared emergency, the Council delegates the authority to DPCPSI to make certain administrative decisions regarding the selection and support of competing grant applications. Every effort will be made to adhere to the Council review procedures. However, if such an approach is not possible then the following delegations will apply:
 1. DPCPSI staff will be able to provide funding for any new (Type 1) or competing (Type 2) applications consistent with the funding policies for a given fiscal year. These funding actions could be taken for any application that does not require individual discussion. Any applications that normally require discussion and special action by the Council will be deferred until its next meeting, or, if possible, resolved by telephone conference.
 2. On a case-by-case basis, the Director, DPCPSI, with the concurrence of the Chief Grants Management Officer of the awarding office, may provide funds for any grant application deemed by the Director, DPCPSI, to be critical to national security or public health.

V. UPDATING COUNCIL OPERATING PROCEDURES

Annually, at the September meeting, the Council will review the Council Operating Procedures and make recommendations for revision, where appropriate.
