Proposed Changes to Council Operating Procedures
(Significant changes)

Pages 7-10, Concept Clearance – Implementing New NIH Policy

- NIH updated its concept clearance policy requiring Council review of a broader array of grant Funding Opportunity Announcements (formerly limited to Requests for Applications) (page 7)

- Multiple necessary changes were made to pages 7-10 to reflect the policy and describe procedures for Council review

- Added definitions of Concept (Reissuance and New) and FOAs covered by the new policy (page 8)

National Institutes of Health
Division of Program Coordination, Planning, and Strategic Initiatives

Proposed Changes to Council Operating Procedures
(Significant changes)

Pages 7-10, Concept Clearance – Council Process / General Principles

- Written materials about concepts will be provided to the Council about 2 weeks in advance of discussion at a meeting

- A Program Officer will present the concept at the Council meeting

- Two Council members will be assigned as discussants; 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.

Proposed Changes to Council Operating Procedures
(Significant changes)

Pages 7-10, Concept Clearance

- Reissuances
    - ❑ For reissuance of FOAs, 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.

    - ❑ If an existing program presented for reissuance 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. The concept would not require re-review if these changes were later incorporated.

National Institutes of Health
Division of Program Coordination, Planning, and Strategic Initiatives

Proposed Changes to Council Operating Procedures
(Significant changes)

Pages 7-9, Concept Clearance

- New Concepts
  - ❑ For new concepts, which are developed over time with input from workshops and meetings, program staff will provide more general background 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.

  - ❑ In the event a new 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.

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Proposed Changes to Council Operating Procedures
(Edits, clarifications, corrections)

Page 1, Introduction – Formatting to streamline text
- Updated text: "The Council provides second-level review of:
all grant and cooperative agreement applications assigned to the Office of Research Infrastructure Programs (ORIP); and grant and cooperative agreement applications as appropriate to programmatic requirements and priorities for the Common Fund (CF), the Environmental influences on Child Health Outcomes (ECHO) program and the *All of Us*SM Research Program."

Page 2, Review of Grant Applications – Clarification
- Updated text: "...Council may make recommendations regarding program balance of the CF and ORIP research portfolios...and the priority with which DPCPSI should attempt to support certain studies."

Proposed Changes to Council Operating Procedures
(Edits, clarifications, corrections)

Page 5, Review of Grant Applications (CF, ECHO, and *All of Us*) – <u>Correction</u>
- Updated text: "The ECB materials include fact sheets/instructions, lists of all applications, summary statements, and any items that may be flagged for special discussion."

Page 7, Applications Identified by Staff for Discussion - <u>Correction</u>
- Updated text: "A quorum must be available either in-person or by phone for the vote."

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Proposed Changes to Council Operating Procedures
(Edits, clarifications, corrections)

Page 7, Council's Advisory Role - Clarification
- Updated text: "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."

Page 9, Authorities Delegated to Staff – Clarification
- Updated text: "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."

NIH National Institutes of Health
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Discussion and Vote

National Institutes of Health
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