

Council of Councils Operating Procedures

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Plan for and Possible Actions from Today's Discussion

- 11:45 AM-12:15 PM - Presentation of the proposed Council Operating Procedures (COP)
- 12:30-1:15 PM - Discussion, possible COP revisions, and a vote.

Possible Actions:

- Concur with the Council Operating Procedures (per Draft, dated 8/20/2012)
- Concur with edits to the Operating Procedures
- If major changes are needed, review the revised Operating Procedures prior to concurrence.

Overall Scope of the Council Operating Procedures

Closed Session

- NIH-Wide Council Operating Procedure
- Procedures Specific to Common Fund (CF) and Office of Research Infrastructure (ORIP) Applications

Open Session

- CF and ORIP Concept Clearance

Authorities Delegated to Staff

Procedures for Revisions to the Operating Procedures

Closed Session Operating Procedures

Council Review of Grant Applications: NIH-Wide Operating Procedures

- Primary purpose of Council: to advise the IC Director (or DPCPSI Director), on the appropriateness of the initial review.
 - Unbiased and informed?
 - May deny funding
- Council also may make recommendations regarding the program balance of the research portfolios and the priority with which NIH should attempt to support certain studies.

Review of Grant Applications: NIH-Wide Operating Procedures (cont.)

Applications must be brought to the attention of Council if they raise any of the following concerns:

- Violation of NIH policies related to animal welfare
- Violation of NIH policies related to the welfare of human subjects
- Concerns about representation of gender and/or minorities and/or children
- Adequate protection to research personnel and/or the environment
- Appropriate biosafety, biocontainment, and security of Select Agents

Also:

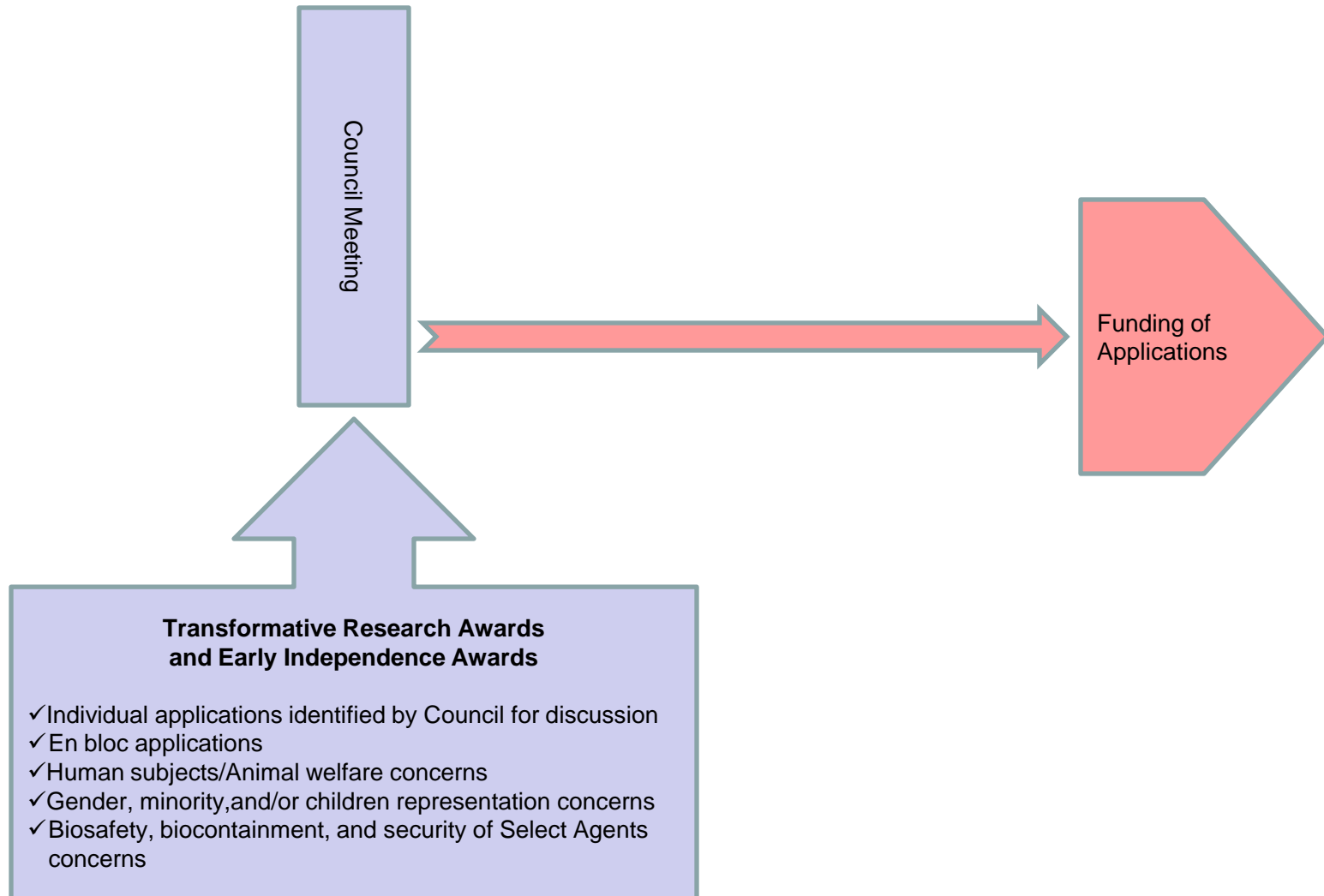
- Applications from foreign institutions
- Letters of appeal that require Council action
- Special Council Review of Pending Applications from Well-Funded Investigators

Review Procedures Specific to CF Applications (TRA & EIA):

No Early Concurrence (EC) process; *en bloc* vote occurs **at the meeting**

- Before the Council meeting, the Council members receive access to an Electronic Council Book (ECB) containing the peer review results for CF Transformative Research Award and Early Independence Award grant applications.
- Also before the meeting, Council members are invited to identify applications that they wish to raise for special discussion at the meeting.
- All CF applications that are not specifically discussed by the Council are recommended by an *en bloc* vote for concurrence with or variance from recommendations of initial review groups.

Council Operating Procedures – CF (cont'd.)



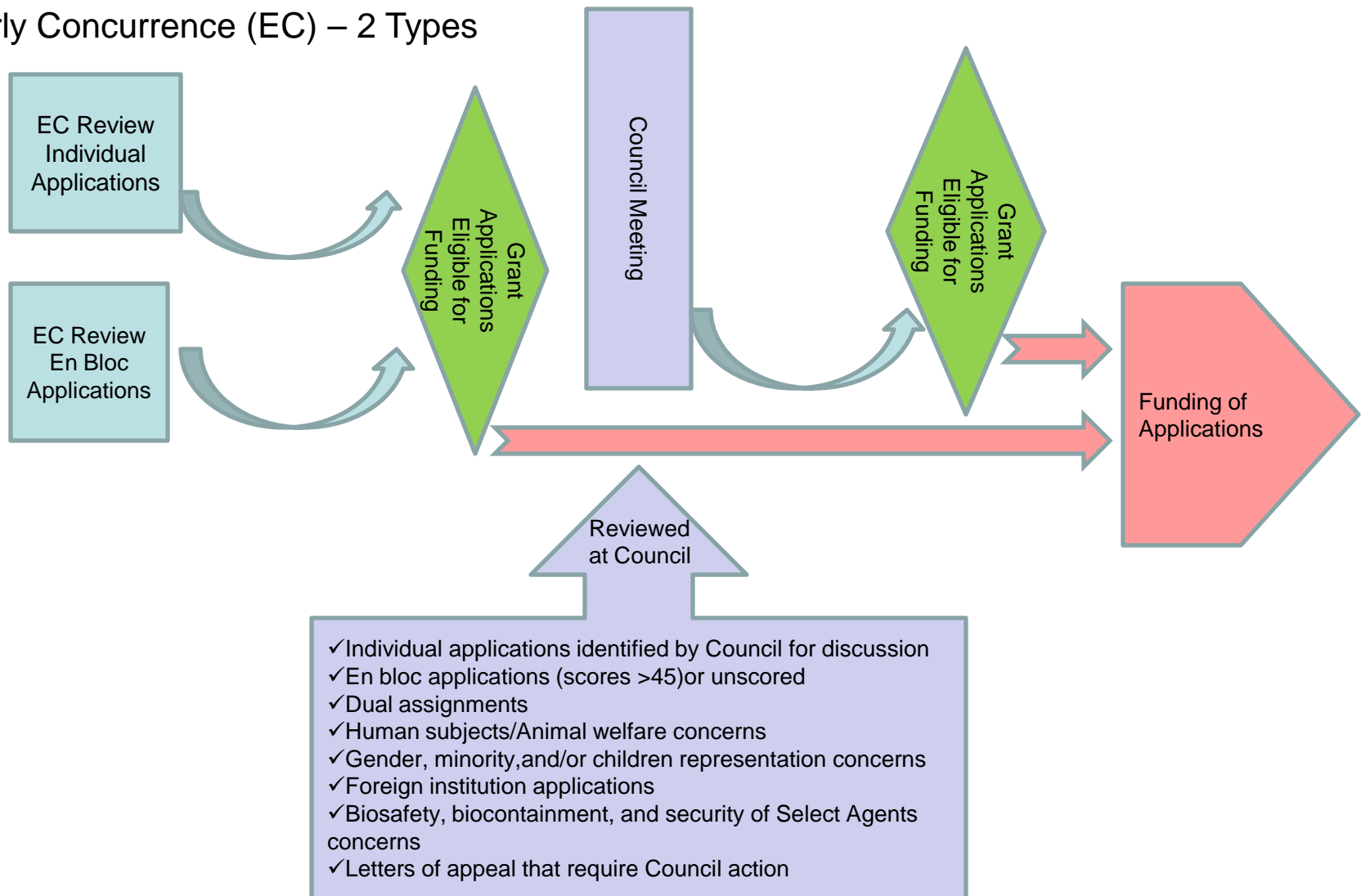
Review Procedures Specific to ORIP Applications

Early Concurrence (EC)/ *en bloc* process; occurs **before the meeting**

- Council Exec. Sec. identifies applications that are eligible for the Early Concurrence (EC) review process, on behalf of the Council.
- Exec. Sec. selects at least two Council members to conduct the EC review for each application.
- Council members can request that any application be removed from the EC list and brought to the full Council for review.
- All Council members have access to the list of *en bloc* applications and summary statements (excluding previously coded, real or apparent conflicts).
- Applications with no special considerations or concerns will be eligible for funding as soon as the Council members selected for expedited review have notified the Exec. Sec. of their positive review.
- A report of the EC recommendations is presented at each Council meeting.

Council Operating Procedures – ORIP (cont'd.)

Early Concurrence (EC) – 2 Types



Open Session Operating Procedures

Advisory Role of the Council in Program Planning and Policy

Program Planning:

- Advise the NIH Director (through DPCPSI) on future plans and directions for scientific research with an emphasis on their public health implications.
- Review objectives, priorities, and accomplishments of DPCPSI's programs.
- Conduct concept clearance for potential Funding Opportunity Announcements (FOAs).

Policy: Participate in discussions of NIH and DPCPSI policies and how they are implemented.

Concept Clearance: Overall Purpose

- To ensure that CF and ORIP initiatives adequately address the objectives defined for these offices.
- To review plans for extramural funding initiatives to ensure that the approaches described for the initiatives will lead to the desired outcomes.

Concept Clearance Operating Procedures Applicable to ORIP

- DPCPSI staff prepare concept presentations for review by the Council. For ORIP concepts, the Council may recommend approval, modification, deferral, or disapproval.
- Concepts are cleared by the Council with a simple majority vote.
- In the event that a concept is judged by the Council to be unlikely to achieve the stated goals for the initiative and/or to be inconsistent with the goals for the program as a whole, the Council describes changes that could be incorporated to make the initiative more likely to achieve the stated goals. The concept would not require re-review if these changes are later incorporated.

Concept Clearance Operating Procedures Applicable to the CF

Council considers broad concepts as they relate to established criteria for new CF programs:

- Is the concept responsive to CF criteria?
 - Votes can be yes, no, or maybe
 - Concepts are cleared by the Council if 50 percent vote “yes” or “maybe.”
- Add comments: What are the most or least transformative aspects of the concept? If it receives a “maybe” vote, how could it be shaped to be truly transformative?

Authorities Delegated to Staff

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- On a yearly basis, the Council delegates to DPCPSI some actions that are normally the responsibility of the Council. These are detailed in the Council Operating Procedures and include but are not limited to:
 - NIH Office of the Director staff may use administrative discretion to take administrative actions in specific areas, as allowed by applicable DHHS, PHS, and/or NIH policies and procedures, and as specified in the Council Operating Procedures.
 - Provide limited interim funding when a recommendation of deferral on a competing continuation application would result in a loss of continuity of the project
 - 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
 - Provide for additional slots on institutional training grants to deal with unusual situations or unexpected opportunities
 - Provide for orderly termination or continuation of support in order to prevent loss of research material or hardship to personnel
 - Make certain administrative decisions regarding competing grant applications in the event of a federally-declared emergency

Procedures for Revisions to the Council Operating Procedures

Revisions to the Council Operating Procedures

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

QUESTIONS?