

# Updated Policy for Concept Clearance of Funding Opportunity Announcements

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## Moderate Alcohol and Cardiovascular Health (MACH) trial

- The MACH trial was a multicenter, randomized clinical trial designed to determine the effects of one serving of alcohol daily (compared to no alcohol intake) on the rate of new cases of cardiovascular disease and the rate of new cases of diabetes among participants free of diabetes at baseline.
- The trial was funded in part by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and in part through private donations to the Foundation for the National Institutes of Health (FNIH).
- Prompted by concerns raised by current NIH and FNIH leadership and a March 2018 report in the media, the Director of NIH requested ACD review of the MACH trial.
- The ACD review revealed that inappropriate actions were taken at multiple steps leading up to the trial, including concept clearance at a closed meeting.

## Reinforcing the Need for Transparent Concept Clearance

- In response to the MACH Trial, the NIH Office of Extramural Research is reviewing the need for revised policies and additional staff training
- Although current NIH policy requires concept clearance for funding initiatives, this policy is being strengthened:
  - To include Program Announcements, for which set aside funds are not typically available.
  - To include clearance for Funding Announcements that are to be re-issued
  - All concept clearance of FOAs (i.e., RFAs, PARs) must be done at an open Council session (or comparable Federal Advisory Committee Act public advisory session)
  - The concept clearance presentation must address the outcomes of any workshop proceedings which informed the FOA development

# Specific Type of DPCPSI Concept Clearances – May 2019

- Concept Clearance for Common Fund Concepts
  - Clearance for Renewal/Reissuance of Programs
    - Program information shared with the Council for review with an opportunity to discuss at the Council meeting
  - New Programs or Initiatives
    - Two reviewers/discussants
    - Discussion by entire Council in open session
- Concept Clearance for ORIP Concepts
  - Clearance for Renewal/Reissuance of Programs
    - Program information shared with the Council for review with an opportunity to discuss at the Council meeting

# Future Concept Clearance Processes

Common Fund Concepts will continue to be discussed and reviewed by the entire Council in open session

- Exception: Concepts for RFAs to be re-issued will be reviewed electronically; Council members will have the opportunity to raise questions as needed

Council “Early Concept Clearance” group with delegated authority to review and approve DPCPSI/ORIP concepts

- Number of group members: 5
- Duration of service (up to 3 years or duration of Council membership)
- Annual update to Council in open session on ORIP concepts that have been cleared by the subgroup
- Council Early Concept Clearance group to be incorporated into Council of Council Operating Procedures for discussion and approval at the Sept 2019 meeting

ECHO Program Concepts will continue to be discussed and review by the entire Council in open session

Questions?



- Extra slide





# NIH Awards – Grants and Cooperative Agreements, not Contracts

FOA (Funding Opportunity Announcement): Publicly available document to announce intention to award discretionary grants or cooperative agreements as a result of competition for funds. RFA, PA, PAR

- **RFA** solicits grant applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside and special receipt dates.
- **PA** solicits new or ongoing applications for extramural activities or programs. May contain reminder of continuing interest or describe modification. Standing submission date are the rule.
- **PAR** (PAs with special receipt, referral, or review dates) and **PAS** (PAs with set-aside funds)

All NIH FOAs are published in the *NIH Guide for Grants and Contracts* (<http://grants.nih.gov/grants/guide/index.html>)