

STATEMENT OF UNDERSTANDING
between
THE NATIONAL ADVISORY COUNCIL FOR HUMAN GENOME RESEARCH
and
THE STAFF OF THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE

I. Review of Grant Applications by the Council

Applications having undergone initial peer review shall be reviewed by the National Advisory Council for Human Genome Research (NACHGR, “the Council”). Exceptions are applications for fellowships, intramural research, inter- and intra-agency agreements and contracts.

- A. Applications not identified for individual consideration are reviewed *en bloc*.
- B. The following types of applications will be presented to Council for individual consideration:
 - All applications for program projects (P01), centers (P20, P30, P41, and P50) and their U counterparts, training (T32), and cooperative agreements (e.g., U01, U24, UM1, U54), on which NHGRI is the primary Institute.
 - Any application identified by Council or staff to be of special concern or posing special policy issues.
 - Any application previously deferred by Council for additional information or for re-review.
 - Any application in which unresolved concerns have been identified by the initial review group (IRG) with respect to animal welfare, human subjects, ethical issues, recombinant DNA, potential biohazards, or the inclusion (or lack) of women, minors, and minorities in clinical research.
 - Any application from a foreign institution for which an award is planned.
 - Any application where the total NIH support for the principal investigator’s active eligible grant(s) already exceeds \$2M total costs and is being considered for funding – aka “[NIH Special Council Review](#)” (SCR), with the following exceptions:
 - i. Based on a discussion and Council vote that took place at the May 20-21, 2019 Council meeting, Special Council Review will not be performed on Centers of Excellence in Genomic Science (CEGS) applications because CEGS applications are required to be highly innovative and transformative in nature. Thus, they already meet the SCR criteria to be unique research opportunities that are distinct from other awards the PI has already received.
 - ii. Active grant awards with project period end dates within 90 days of the Council meeting will not be included in the \$2M total cost calculation for SCR consideration.
- C. The following options are available to Council for an application that is identified for individual consideration:
 - Concurrence with the recommendation of the initial review group (IRG) with or without changes in time or amount.
 - Recommendation for high or low program priority for funding consideration.
 - Deferral of the application for re-review because of an inadequate initial review.

- Deferral for additional information and reconsideration at a subsequent meeting.
- D. NIH has authorized the use of an expedited review process to improve the efficiency and timeliness of making awards. This process, known as Expedited Council Concurrence (ECC), is expected to occur once each Council round, approximately four weeks before the scheduled NACHGR meeting. Generally, NHGRI utilizes ECC for the following types of applications:
 - unsolicited ELSI applications (excluding ELSI T32 training grant applications),
 - SBIR/STTR applications (R41, R42, R43, R44),
 - conference applications (R13),
 - career development applications (e.g., K01, K08, F99/K00, and K99/R00),
 - unsolicited research applications (R01, R03, and R21),
 - unsolicited education applications (R25), and
 - any application previously excluded from a complete Council list due to an administrative error, and other select applications where individual consideration by Council is not required.

The ECC Subcommittee will consist of 3-4 Council member with broad expertise. Volunteers from Council will be recruited by the Council Executive Secretary at the September Council meeting and will serve on the ECC Subcommittee for the remainder of their Council term. General procedures are as follows:

- NHGRI staff will notify the ECC Subcommittee members by email when an expedited review is needed, typically one month prior to the February, May, and September Council meetings.
- The following information will be provided for applications considered for ECC: Application Number, Principal Investigator, Institution Name, Project Title, Impact Score and/or Percentile Rank.
- Subcommittee members will be expected to respond within seven days. If an ECC member does not respond within seven days of notification, that member will be considered to have abstained from the vote, and the decision will be based on the majority of the votes received.
- Any ECC Council member(s) may specify an application should go to full Council consideration without the need for justification. In that case, the application will go to the next regular Council meeting for individual consideration. Otherwise, the subcommittee members will be asked to approve all the applications presented to them for Expedited Council Concurrence.
- All recommendations made by the ECC Subcommittee will be documented and presented to the full Council for its information at the next Council meeting

II. Staff Administrative Authorities

During the course of a research project, a principal investigator may request additional funds through an administrative supplement, as long as the work proposed does not expand the scope of the project beyond that which was peer reviewed and approved by Council. Staff of the National Human Genome Research Institute will analyze and review the budgets of all administrative supplement applications before issuing a grant award. Special note is made of any items requiring adjustment of amounts or other terms and conditions. Staff will negotiate

appropriate adjustments for such things as overlapping or duplicate support, inaccurate cost estimates, or adjustments necessitated by a change in the base used for the recovery of indirect costs. Also, staff will make adjustments to reconcile inconsistencies between recommended budgets and recommended activities.

Supplements for initiatives to NHGRI awards that are within the scope of the award, but which are to be funded by institutes or agencies other than NHGRI, do not need Council approval. The supplement will be documented and reported to Council for its information at the first appropriate opportunity. NHGRI may provide supplements to grant awards funded by other NIH Institutes or HHS agencies as long as NHGRI is assigned as a dual IC, and the grant has been approved by an NIH Advisory Council.

The staff may make supplemental awards that are above the level recommended by the Council at the time of the initial award, as long as the grant has been approved by the Council. These types of administrative supplements can be made to a grant:

- To take advantage of unexpected scientific opportunities or public health needs that have the potential to accelerate the completion of scientific goals.
- To provide additional training and career support, such as training slots to T32s, childcare supplements beyond 25% of costs, or re-entry into biomedical and behavioral research careers.
- To provide an extension with funds. The extension may not exceed one year. For extensions less than one year, the amount shall not exceed the current level of support, prorated for the duration of the extension. An extension can be made when a competing continuation application is deferred for re-review, or in exceptional situations; e.g., to provide for orderly termination or to maintain a research group in anticipation of future funding when a competing continuation application will not be paid.

All supplement requests will be reviewed by the NHGRI Extramural Leadership Team (ELT) and must be approved by the ELT before an award can be made. All supplement awards, regardless of the amount, will be reported at the next Advisory Council meeting.

All of the above circumstances will be documented and presented to the Council for its information at the next Council meeting.

Requests for administrative increases that exceed Council-delegated amounts will be referred to the Council for advice and recommendation.

Requests that do not exceed Council-delegated amounts will be brought to Council if they involve a marked expansion or significant change in the content of a grant, or if staff determines that they involve issues on which Council should be consulted.

NHGRI staff will determine whether the urgency is sufficient to warrant interim consultation with the Council by e-mail or telephone, whether the request can be considered at the next Council meeting, or whether the request should be submitted for formal peer review.

III. Exceptional Situations

Expedited Council review of certain requests between regularly scheduled Council meetings may be initiated under certain conditions. These conditions may include time-sensitive requests, applications responding to Requests for Applications or Letters of Invitation, or unsolicited grant applications, believed by the Director, NHGRI, or Director, NIH, or designee, to address a public health emergency or representing opportunities in biomedical research that would have a significant public health or trans-NIH impact.

In the case of a crisis or state of emergency (pandemic, terrorism, acts of nature, etc.), or to reduce travel burden for Council members, Council meetings can be conducted virtually using secure commercial meeting platforms. Every effort will be made to ensure that three or more Council members with the appropriate expertise and representation will review and approve applications for *en bloc* or individual consideration. Procedural instructions will be provided by NHGRI at the appropriate time.

To be approved by the National Advisory Council for Human Genome Research on June 18, 2025. This statement will be reconsidered by Council once a year.¹

¹ Last modified on June 10, 2025