

**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

All applications having undergone initial peer review shall be reviewed by 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 the 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 and 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) will exceed \$1M direct costs and is being considered for funding – aka "[NIH Special Council Review](#)" (SCR). 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.
- 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.

- Deferral of the application for re-review because of an inadequate initial review.
 - Recommendation for high or low program priority for funding consideration.
 - 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, several 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, conference applications, career development applications (e.g., K01, K08 and K99/R00), small budget unsolicited research applications (R03 and R21), and education applications (R25), applications previously excluded from a Council Master 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 volunteers 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, Principle 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 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 NHGRI's Council. Two types of administrative supplements can be made; either one, or both, can be made to a grant.

- 1) To take advantage of unexpected scientific opportunities that have the potential to accelerate the completion of scientific goals.
- 2) 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; for example, 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 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 to the NACHGR at the next Advisory Council meeting.

There are other special categories of supplement awards that the staff can make. These include:

- 1) To respond to NIH-wide initiatives and the NHGRI Action Plan, such as those to increase the number of women, under-represented minorities, and individuals with disabilities pursuing biomedical research. For T32 awards, slot(s) may be added temporarily to accommodate additional slots not originally approved in the competitive application.
- 2) The trans-NIH Research Supplements to Promote Diversity in Health-Related Research and to Promote Re-Entry into Biomedical and Behavioral Research Careers does not provide research support for individuals already supported on a grant. The goal is to increase diversity in the workforce and to encourage scientists who have had a hiatus in their research careers to update their skills. These supplements support such individuals to conduct research in the areas of genomic science, genomic medicine and ELSI research. Authorization is given to fund Diversity and Re-Entry supplements for

scientists supported by grants from NHGRI and other NIH Institutes and Centers, regardless of the National Advisory Council or Board that approved the parent grant application. Support can be provided for personnel, equipment and research supplies.

- 3) The Medical Scientist Training Program (MSTP) program is a collaboration between the NIH's intramural Graduate Partnership Program and NIGMS' extramural Medical Scientist Training Program. The intramural program pays for the thesis research conducted at NIH, and participating NIH Institutes and Centers co-fund extramural training slots on NIGMS' MSTP training grant to pay for program participants to complete their medical education. NHGRI will support up to two trainees per year. The commitment to the number of trainees will be reviewed periodically and decisions made based on NHGRI's anticipated budgetary situation.

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 which 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, 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 government declared crisis or state of emergency (pandemic flu, terrorism, acts of nature, etc.), or a regularly-scheduled Council meeting is cancelled due to a government shutdown, then Council review can be conducted electronically (by teleconference, email and/or secure website). 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 and/or individual consideration. Detailed procedural instructions would be provided by NHGRI at that time.

Approved by the National Advisory Council for Human Genome Research on February 10, 2020. This statement will be reconsidered by Council once a year.¹

¹ Last modified on July 18, 2019