

**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 review shall be reviewed by the Council. Exceptions are applications for fellowships, intramural research only, 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), training (T32) and cooperative agreements (U01, UH2/UH3, U41 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, minorities or children 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](#)".
- 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 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 in an effort to improve the efficiency and timeliness of making awards. This process, known as Expedited Council Concurrence (ECC) will usually occur once each Council round, several weeks before the scheduled NACHGR meeting. Generally, NHGRI utilizes ECC for SBIR/STTRs, applications excluded from a Council Master List due to administrative error, and other select applications where individual consideration by Council is not required. The ECC Sub-Committee will consist of 2-3 Council member volunteers with broad representation. Volunteers from Council will normally be recruited by the Council Executive Secretary at the September Council, and will serve on the ECC Sub-Committee for the remainder of their Council term. General procedures are as follows:
- NHGRI staff will notify the ECC Sub-Committee members by email when an expedited review is needed, typically a month prior to the February, May, and September Councils.
 - 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.
 - 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.
 - All recommendations made by the ECC Sub-Committee will be documented and presented to the full Council for its information at the next Council meeting.

II. Staff Administrative Authorities

Staff of the National Human Genome Research Institute analyze and review the budgets of all 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.

Under the following circumstances, the staff may make supplemental awards that are above

the level recommended by the Council:

- To take advantage of unexpected scientific opportunities that have the potential to accelerate the completion of scientific goals. In such cases, the increase per project period will be limited to \$150,000 or 25 percent of the total costs approved by Council, whichever is greater.
 - Notwithstanding the 25 percent rule, increases for large projects (e.g. sequencing centers) will not exceed \$1,000,000 total costs without Council approval.
 - A special exception to this 25 percent rule may be made in the case of one time equipment costs which will increase the speed and efficiency of projects.
 - Supplements for initiatives to NHGRI awards that are within the scope of the award but are to be funded by institutes or agencies other than NHGRI, are allowed without prior Council approval. The supplement will be documented and reported to Council for its information at the first appropriate opportunity.
- To provide an extension with funds:
 - when a competing continuation application is deferred for re-review;
 - 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;
 - The extension shall not exceed one year and the amount shall not exceed the prorated level of current support.
- 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 trainees not originally approved in the competitive application.
- 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 area of genomics and ELSI research. Authorization is given to fund supplements for scientists supported by grants from the NHGRI and other NIH Institutes and Centers, regardless of the National Advisory Council or Board that approved the parent grant application. Support is provided for personnel, equipment, and research supplies.
- 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 first appropriate opportunity.

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 nevertheless 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 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.) Council review will be conducted using secure electronic communication methods. Every effort will be made to secure NACHGR members with appropriate expertise and representation for a panel of three or more to 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 on Human Genome Research on February XX, 2014. This statement will be reconsidered by Council once a year.