2017 Statement of Understanding

Between the Staff of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Advisory Child Health and Human Development Council

The mission of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) includes support of basic, clinical, and applied research, and research training. The Institute promotes a broad range of approaches to scientific areas related to its mission and encourages the ideas and talents of investigators who accomplish this mission.
To help achieve the goals of the Institute, the National Advisory Child Health and Human Development Council is charged with the responsibility of advising, consulting with, and making recommendations to the Director, NICHD, on matters relating to the research and research support activities and functions of the Institute. The roles and responsibilities of the Council members include secondary review of grant applications, with a focus on NICHD scientific program priorities and program balance.

I. Council Membership and Structure

The Council consists of 24 members. Six are non-voting, *ex officio* members: the Secretary, Department of Health and Human Services (DHHS); the Director, NIH; the Director, NICHD; the Chief Medical Director, Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs (or designee); and a representative, Maternal and Child Health Bureau. The Secretary, DHHS, appoints 18 members. Twelve of these members are representatives of health and scientific disciplines (including two individuals who are leaders in the fields of public health and the behavioral or social sciences) and six are from the general public. A member of the National Advisory Board on Medical Rehabilitation Research, National Center for Medical Rehabilitation Research, NICHD, acts as a non-voting liaison representative to ensure adequate communication on critical issues of concern to both committees. Appointed members serve for four-year terms and are not eligible for reappointment to the same Council until two years after the date of expiration of their term of office. A member may serve for 180 days after the date of expiration of his/her term. The Secretary, DHHS, selects the Council Chair. Ad hoc Workgroups will be formed on an as-needed basis to involve Council members in considering specific issues and to form recommendations regarding those issues for the Institute.
A council quorum consists of a majority of the 18 appointed members. *Ex officio* and liaison members are non-voting members of the Council.
Council meetings typically consist of an open (public) session for the discussion of scientific and policy issues, and a session closed to the public for the second-level review of grant and cooperative agreement applications, as provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463.

II. Secondary Review of Grant Applications (Summary Statements)

Secondary review of grant applications is carried out by Council in the closed session.
The following actions may be considered individually by the Council:

- Conversion of highly meritorious R01 awards to R37 Method to Extend Research in Time (MERIT) awards;
- Extension of the initial R37 MERIT Award;
- Applications from foreign institutions within a fundable range;
- Requests to transfer an existing award to a foreign institution or between foreign institutions;

- Staff recommendations for co-funding;
- Scientific program plans for funding under Requests for Applications (RFA);
- Summary statements of special interest or posing special policy issues;
- Applications of High Program Priority (HPP) and/or applications of Low Program Priority (LPP) proposed by NICHD Staff;
- Staff recommendations for appeals of initial peer review; and
- Applications from Principal Investigators with total NIH grant support already in excess of $1.0M per year (direct costs).

Summary statements raising concerns related to human subjects, animal welfare, and inclusion of children, gender and/or minorities, as well as requests for more than $500,000 in direct costs, also will be brought to the attention of the Council if the application is eligible for NICHD funding. At the closed session of the full Council, summary statements not requiring individual discussion are treated *en bloc*. Appeals that have been resolved prior to the meeting are presented as information items. Any Council member may request that an individual summary statement or appeal be discussed individually by the Council.
As required by P.L. 109-482, The NIH Reform Act of 2006, all research grant and cooperative agreement applications must undergo Advisory Council/Board review and approval prior to funding. Fellowship applications are not required to undergo Advisory Council review. However, Section 487 of the PHS Act requires Kirschstein-NRSA institutional research training grants (T32) to be reviewed and approved by the appropriate Advisory Council/Board.

III. Administrative Decisions and Actions that Do Not Require Council Recommendation

NICHD staff evaluates and reviews all applications before issuing a grant award. Staff negotiates appropriate adjustments to reconcile inconsistencies between recommended budgets and recommended research activities. All adjustments reflect the latest determination of actual or estimated needs of the project, Council recommendations, program relevance, the current NIH cost management plan, and the availability of funds to support the research effort.
The following staff actions do not require Council recommendations, but may be presented to Council for information purposes:

- Change of principal investigator or program director on a grant that will continue to receive support at the same grantee institution;
- Change of institution by a principal investigator who will receive previously recommended support for the grant transferred to the new institution, except for transfers to a foreign institution which require Council concurrence; and
- Applications deferred for re-review prior to the Council meeting.

IV. Options Available to the Council

The Public Health Service Act requires that funding of a grant application may occur only after it has been properly reviewed and the Council has concurred with the recommendation of the scientific review group (SRG).
The Council may not change the scores assigned by the SRG. The following options are available to the Council for each application that is identified for discussion:

- Concurrence with the SRG recommendation;
- Non-concurrence with an SRG recommendation based on scientific/technical merit. The application may be deferred for SRG reconsideration of scientific/technical merit;
- Non-concurrence with an SRG recommendation based on factors other than scientific/technical merit considerations;

- Recommendation of high program priority (HPP). An HPP designation elevates the relative funding position of an application. HPP funding generally is provided based on the unique or special opportunity presented by the application and its relevance to the NICHD program of research;
- Recommendation of low program priority (LPP). An LPP designation reduces the relative funding position of an application based on low relevance to the NICHD program of research; and
- Deferral to obtain additional information for Council consideration at a subsequent meeting.

V. Expedited Review of Meritorious Applications

The most meritorious NICHD applications may be awarded following an SRG meeting and prior to a formal Council meeting provided that the applications selected:

- are R01s, R03, R13, R21, R15, R24, R25, all Career (K), T32, R41, R42, R43 or R44s;
- have the summary statements available;
- are scored with a percentile between 0.1% and 5.0%, or a score of up to 19 if not percentiled;
- cost less than $500,000 direct costs in each year;
- have no SRG concerns regarding the participation of humans and/or animals;
- adequately address scientific requirements for inclusion of minorities, gender, and children;
- were not submitted in response to an RFA; and
- were submitted by a domestic, not a foreign, institution.

Four Council members, on behalf of the full Council, will be selected by the Council Chair to provide concurrence for applications eligible for expedited award. The summary statements for each application under consideration for expedited award will be available to these members on the Council Members Website. These members will vote on-line whether or not each application should be considered for an expedited award. In addition, all members of the Council will be able to view these summary statements during the voting period and may comment directly to one of the four voting members if a concern is noted.
Eligibility for expedited award will require concurrence by all four voting members. Any application, within the criteria stated above, that does not receive concurrence will be considered by the full council, either as part of the *en bloc* portfolio or in discussion.

VI. Interim Review

Council review of grant applications between regularly scheduled Council meetings may be initiated under certain conditions. These conditions may include applications responding to an RFA or unsolicited grant applications, believed by the Director, NIH, or the Director, NICHD, to address a public health emergency or to represent opportunities in biomedical research that would have a significant public health or trans-NIH impact.

VII. Concept Review (During Open Session)

Descriptions of concepts for grant solicitations proposed by NICHD program staff for development and publication are presented to Council for review and recommendation during open session. Council may take the following actions in concept review:

- approval;

- disapproval; or
- approval with recommendations for specific modifications.

VIII. Emergency Procedures

In order to carry out its responsibilities during a declared emergency such as an avian flu epidemic, NICHD may consider various options to assure that Council fulfills its mandated role, including the following, separately or in combination:

- teleconference the Council proceedings;
- hold only closed session for secondary review of applications;
- utilize on-line voting;
- change the meeting location; and/or
- hold an Internet-assisted meeting.