The Advisory Committee to the Director High-Risk High-Reward (HRHR) Research Working Group (ACD WG) provided a set of recommendations in its final draft report presented at the ACD meeting on June 13, 2019. The major thrust of the ACD WG's recommendations was to encourage diversity of many different types, namely: scientific topics, institutions, and PI gender, race, and ethnicity. The specific recommendations include actions to be taken during the application phase (Outreach), the review phase (Addressing Bias in Review), the award selection phase (Ensuring Institutional Diversity), the post-award phase (Addressing Sexual Harassment and the Workplace), and the evaluation phase (Evaluating Outcomes). The committee also recommended that new initiatives be considered. We provide implementation strategies and additional thoughts for each of these below.

OUTREACH: A NUMBER OF THE ACD WG'S RECOMMENDATIONS REGARDED OUTREACH TO THE COMMUNITY IN THE FORM OF WORKSHOPS, WEB CONTENT, AND CONFERENCE PRESENTATIONS.

Recent and planned efforts that are responsive to these recommendations include:

Outreach to Under-Represented Minority (URM) groups:

- *Network of Minority Health Research Investigators (NMRI) Meeting*—April 25, 2019 and annually hereafter
    - Program staff addressed questions about the HRHR programs and funding opportunities with potential URM postdocs and faculty applicants that shared interests in research/disease with a minority health focus
- *SACNAS*—October 31 – November 2, 2019 and annually thereafter
    - HRHR team member is registered for the Conference and Booth. Oral presentation request has been accepted by organizers.
- *ABRCMS*—November 13-16, 2019 and annually thereafter
    - HRHR team member is registered for Conference and Booth to distribute program materials. Oral presentation request has been accepted by organizers.
- Outreach through partner organizations
    - AAMC, HHMI, and the Robert Wood Johnson Foundation convene URM fellows annually. Hannah Valantine is helping OSC establish relationships with the organizers of these meetings so that we can provide information about the HRHR program.

Outreach to Institutions that may not be aware of the HRHR Program:

- *NIH Regional Seminars*
    - HRHR has participated in every Regional Seminar (held twice a year) since October 2016. At the May 2019 meeting, HRHR program officer and communications team member guided interested applicants to the most appropriate HRHR programs relevant to their career stage; informational materials were provided to university administrators and potential applicants
    - To broaden the visibility of the HRHR Program, OSC worked with Regional Seminar organizers to provide more opportunities to highlight the program in

the seminars, including
- Slides and discussion of the HRHR program by Mike Lauer during his plenary talk
- Slides and verbal mention of the HRHR program during relevant session talks
- HRHR program slide included on the slide rotation displayed on screens between talks and sessions
- HRHR program advertisement in the NIH Regional Seminar agenda book (as done previously)
- HRHR program informational booth with graphic displays, slide display, and flyers and the opportunity to speak to HRHR program staff (as done previously)

- *The NIH IDeA Regional Conferences (annual attendance planned)*
  - Central Regional Conference-June 12-14, 2019
    - OSC provided slides to attending NIGMS staff regarding the Early Independence and New Innovator initiatives
  - Talks have been confirmed for the HRHR Program Leader to deliver 20-30 minute presentations at the other NIH IDeA regional conferences
    - Northeast Regional Conference-August 14-16
    - Western Regional Conference-October 6-9
    - Southeast Regional Conference-November 6-8

Outreach to the Behavioral and Social Science Community

- *The Association for Psychological Science*—May 25, 2019
  - The HRHR funding opportunities were advertised to a wide range of psychological science researchers during a round table discussion featuring another Common Fund program, Science of Behavior Change.
- The OSC and OBSSR Directors co-wrote a blog in the OBSSR Connector Monthly to encourage BSSR applicants. This may become an annual post when the FOAs are issued each year.
- The Deputy Director of OBSSR has joined the NIH HRHR Working Group to lend expertise in the identification of reviewers, the development of pay plans, and in discussions pertaining to how the program might be managed most effectively.

Broad outreach to all communities

- *Conference presentations by Common Fund HRHR WG members*
  - Common Fund HRHR WG members will be re-encouraged to describe the HRHR program and disseminate informational materials at conferences they are attending.
- *IC blogs highlighting the HRHR program*
  - Common Fund HRHR WG will be encouraged to have their ICs post blogs

describing the HRHR program. One such blog has been posted by NCCIH: NCCIH HRHR blog.

- *Informational webinars* – July 2019
  - o As part of an ongoing bi-annual event, HRHR team members will host informational interactive webinars, one for each of the four initiatives. A recommendation by the ACD WG to host workshops in which institutions can send 1-2 students to learn about the EIA initiative would be difficult to implement and would seem to have narrow impact. The informational webinar for the EIA initiative should address the underlying need reflected in the recommendation.

Enhanced online information

- *Examples of successful HRHR applications*
  - o HRHR awardees will be asked to volunteer redacted versions of their applications for posting.
- *Broad advertisement on Science website*
  - o A banner advertisement was placed on the Science magazine home page to publicize the HRHR program and upcoming application receipt dates.
- *Targeted emails*
  - o OSC is working with OER to determine feasibility and process for targeted emails to recipients of F32 grants and PIs of T32 training grants to publicize the Early Independence and New Innovator FOAs.

BIAS DURING REVIEW: THE ACD WG WAS CONCERNED ABOUT THE POTENTIAL FOR BIAS AGAINST LESS RESEARCH-INTENSIVE INSTITUTIONS, AGAINST CERTAIN TOPICS (BSSR AND CLINICAL RESEARCH), AGAINST, WOMEN, AND AGAINST UNDER-REPRESENTED MINORITIES.

Recommendations to address possible bias during review include:

- *Provide reviewer training*
  - o OSC will work with CSR to ensure that reviewers continue to receive training to reduce unconscious bias and that SROs continue to remind reviewers to guard against such bias. Also, to encourage diversity of applicants and to clarify with reviewers that this is a priority, the FY2020 FOAs have included stronger language of inclusivity: "Applications from talented researchers with diverse backgrounds underrepresented in research, including underrepresented racial and ethnic groups, persons with disabilities, and women are strongly encouraged to apply to this Funding Opportunity Announcement. Outstanding research is conducted at a broad spectrum of institutions. In seeking to support the highest quality research, this Funding Opportunity Announcement encourages applications from the full range of eligible institutions, including those that may serve primarily underrepresented groups, those that may be less research-

intensive, and from all domestic geographic locations."
- *For the Pioneer Awards and Early Independence Awards, withhold the biosketch from the first phase of review to focus more on the approach and more on the person in the second phase*
  - OSC has had preliminary internal discussions about piloting anonymized review and will work with OER and CSR to determine the best way to move forward with such a pilot.
- *Improve diversity of reviewers*
  - OSC will work with CSR to ensure that efforts to appropriately enhance reviewer diversity in all substantial aspects are strengthened and that the reviewer diversity is closely monitored.
- *Reduce topic bias*
  - The FY2020 FOAs have included language that is more explicitly inclusive: "applications in all topics relevant to the broad mission of NIH are welcome, including, but not limited to, topics in the behavioral, social, biomedical, applied, and formal sciences and topics that may involve basic, translational, or clinical research."
  - To ensure appropriate reviewer expertise is available and matched to applications, OSC will continue to work with CSR to ensure that review panels are balanced in terms of topic expertise. The review processes used will continue to ensure that each application will be reviewed by at least some assigned reviewers with broad expertise in the topic of the application; however, given the nature of the review process, which seeks input from reviewers with a variety of scientific perspectives, it is not possible for all reviewers to have topic expertise. As noted above, we have also engaged OBSSR to help identify reviewers for BSSR applications.

ENHANCING INSTITUTIONAL DIVERSITY DURING THE AWARD SELECTION PROCESS: IN ADDITION TO ENHANCED OUTREACH AND ATTEMPTS TO REDUCE BIAS DURING THE REVIEW, THE ACD WG RECOMMENDS ADDRESSING THE CURRENT INSTITUTIONAL BIAS IN THE AWARDS BY MAKING INSTITUTIONAL DIVERSITY A PROGRAM PRIORITY.

- Future FOAs will state the importance of supporting innovative science broadly across US institutions and will explicitly include breadth of institutional impact as a programmatic priority for funding (language has been approved by OGC, relevant text underlined):

  From the FOA Description section:

  > In order to support the most innovative and impactful research, the NIH recognizes the need to foster a diverse research workforce across the nation. Applications to this award program should reflect the full diversity of potential PI/PDs, applicant institutions, and research areas relevant to the broad mission of NIH. Talented researchers from diverse backgrounds, including those from underrepresented racial

and ethnic groups, persons with disabilities, and women are strongly encouraged to work with their institutions to develop applications for this Funding Opportunity Announcement. As outstanding research is conducted at a broad spectrum of institutions, it benefits the national scientific enterprise to support exceptionally innovative and impactful science that represents this breadth. Therefore, this Funding Opportunity Announcement encourages applications from the full range of eligible institutions, including those serving primarily underrepresented groups, those that may be less research-intensive, and from all domestic geographic locations. Applications are welcome in all research areas broadly relevant to the mission of NIH. These areas include, but are not limited to, the behavioral, medical, natural, social, applied, and formal sciences. Research may be basic, translational, or clinical. The primary requirements are that the research be highly innovative and have the potential for unusually broad impact.

From the FOA Review and Selection Process section (example from the Pioneer Award FOA, relevant text underlined):

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities, including
    - The potential for the investigator to lead groundbreaking and broadly impactful research, despite its inherent risks.
    - Unusually cross-cutting science.
    - Scientific balance in the portfolio of Pioneer Award-supported research.
    - Potential to invigorate exceptionally innovative and impactful science broadly across the nation.
    - Conformance to the clinical trial research policies of the administering Institute or Center.

ENSURING A WORK ENVIRONMENT THAT IS FREE FROM HARASSMENT: THE ACD WG RECOMMENDS THAT HRHR GRANTEE ORGANIZATIONS PROVIDE ASSURANCES OF HAVING EFFECTIVE POLICES TO PRESERVE A HARASSMENT-FREE ENVIRONMENT AND THAT SUCH ORGANIZATIONS ALERT AND WORK WITH NIH WHEN THEY BECOME OF AWARE OF HARASSMENT-RELATED FINDINGS INVOLVING HRHR AWARDEES.

Since the issues extend well beyond the HRHR program to all of NIH, OSC will ensure that policies established by NIH as a whole are reflected in FOAs and Terms of Award.

EVALUATING OUTCOMES: THE ACD WG RECOMMENDS A FORMAL EVALUATION OF THE TRANSFORMATIVE RESEARCH AWARD PROGRAM.

OSC has commissioned an independent evaluation of the Transformative Research Award (TRA) initiative outcomes. The Science and Technology Policy Institute (STPI), which conducted the

evaluations for the Pioneer Award and New Innovator Award initiatives, is conducting the evaluation. The TRA evaluation was launched April 1, 2019 and is expected to conclude November 30, 2020. Concurrent with the TRA evaluation, STPI is also conducting an evaluation of the Early Independence Award (EIA) initiative outcomes.

NEW INITIATIVES: THREE NEW NIH-WIDE OR COMMON FUND INITIATIVES WERE RECOMMENDED.

OSC does not plan to implement recommendations for these new initiatives, in part because the HRHR program currently utilizes ~30% of the Common Fund budget, and implementation of new initiatives would undermine support for other programs. The current percentage of the CF budget devoted to the HRHR program has been steady for several years, and we feel that this is an appropriate fraction of the Common Fund to devote to investigator-initiated projects. We recommend that these initiatives be considered by the ICs; for each one, we offer the following thoughts:

- **Special HRHR program that requires collaboration between under-resourced institution and resourced institution**
  - A multi-IC program to partner investigators from under-resourced URM institutions with R01-funded investigators exists through the SCORE program. It is not clear to us why this type of partnership would be needed within the HRHR program; multi-institution partnerships can already be supported through the Transformative Research Award program. The other HRHR initiatives are restricted to a single PI due to the focus on the investigator for those awards; these award types would not be well-suited for multi-PI partnerships.
- **Special track or separate HRHR program for clinical outcomes**
  - All four HRHR FOAs are "Clinical Trial Optional." About 3% of applications in 2019 were PI-identified as involving a clinical trial. The general compatibility of clinical research with "high risk" and "no preliminary data" has been the subject of repeated discussion over the years. The conclusion has been that clinical projects tend to rely on solid preliminary data from pre-clinical experiments and therefore are best supported through R01s or other IC-funded mechanisms. This was also discussed by the ACD WG, and some members seemed to reach the same conclusion. If a "Clinical Trial Only" HRHR-type initiative is to be launched, we feel this would be best implemented through specific IC initiatives, where the definition of "high risk" can be tailored to their respective clinical research contexts and needs.
- **Apply New Innovator features to a special award type for ESIs; in concert with the NGRI ACD WG recommendations, expand ESI funding opportunities that do not require preliminary data**
  - This recommendation is being addressed via the NIH-wide Katz Award, which will support ESIs proposing research without preliminary data.