

- *Initial assessment report:* <https://www.fda.gov/media/108866/download>
- *Interim assessment report:* <https://www.fda.gov/media/138662/download>
- *Final assessment report:* <https://www.fda.gov/media/154873/download>

The initial assessment served as a baseline, evaluated the state of FDA human resource operations, identified root causes of challenges, and provided recommendations related to recruitment and hiring. Unlike the subsequent evaluations, the initial assessment did not evaluate employee retention efforts. The interim and final assessments documented progress from the previous assessment(s) related to recommendations from the initial assessment, program milestones, metrics, and other aggregated feedback from internal HR/HC customers and participants and provided additional recommendations. The current assessment builds upon the findings from the three previous assessments with a focus on changes that have improved FDA's hiring and retention outcomes and challenges that remain. The current assessment also expands beyond the scope of the previous assessments to include the pre-employment onboarding process. This assessment report includes metrics related to recruiting and retention in the human drug review program, including specific targeted scientific disciplines, attrition, and utilization of pay authorities. The report also includes the contractor's findings and recommendations on further enhancements to hiring and retention of staff for the human drug review program. To view the assessment report, please visit: <https://www.fda.gov/media/188083>.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to hiring and retention in the FDA human drug review program. The independent contractor will present their findings and recommendations that are outlined in the hiring and retention assessment report, and FDA will provide its perspective on the independent contractor's findings and recommendations. To view the assessment report, please visit: <https://www.fda.gov/media/188083>.

III. Participating in the Public Meeting

Registration: To register for this hybrid public meeting, please visit the

following website: https://FDAPublicMeeting_PDUFAVII_BsUFAlII_HiringandRetention.eventbrite.com.

Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending the public meeting must register by September 15, 2025, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Tamar Bailey, 301-796-6645, CDERProgramEvaluation@fda.hhs.gov no later than September 15, 2025, 11:59 p.m. Eastern Time.

Opportunity for Public Comment: During online registration, you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations during the meeting must be received via registration by September 15, 11:59 p.m. Eastern Time. Onsite registration for public comments on the day of the public meeting will not be provided. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 17, 2025. If selected to present at the public comment session, any presentation materials must be emailed to CDERProgramEvaluation@fda.hhs.gov by September 19, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast to registered attendees. To view the webcast of this public meeting, please register at https://FDAPublicMeeting_PDUFAVII_BsUFAlII_HiringandRetention.eventbrite.com (see "Registration"). Please provide complete contact information for each

attendee, including name, title, affiliation, and email.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment>.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16245 Filed 8-22-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Supporting Fairness and Originality in NIH Research Applications

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on August 5, 2025. That notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

DATES: This policy is effective for applications submitted to the September 25, 2025, receipt date and beyond.

FOR FURTHER INFORMATION CONTACT: Further information about this policy notice may be directed to Dr. Lyric Jorgenson, NIH Office of Science Policy, at (301) 496-6837 or (SciencePolicy@od.nih.gov).

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 5, 2025, in FR Doc. 2025-14744, on page 37531, as found within the **SUPPLEMENTARY INFORMATION** section. Currently reads "https://grants.nih.gov/grants/policynihgps/html5/section_2/2.1.2_recipient_staff.htm" and is corrected to read: "https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.2_recipient_staff.htm". Also "https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.27_research_misconduct.htm" and is corrected to read: "https://grants.nih.gov/grants/

policy.nih.gov/html5/section_4/4.1.27_research_misconduct.htm".

Policy

NIH will not consider applications that are either substantially developed by AI, or contain sections substantially developed by AI, to be original ideas of applicants. If the detection of AI is identified post award, NIH may refer the matter to the Office of Research Integrity to determine whether there is research misconduct while simultaneously taking enforcement actions (see: <https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.339>) including but not limited to disallowing costs, withholding future awards, wholly or in part suspending the grant, and possible termination.

NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year. This policy applies to all activity codes except T activity codes and R13 Conference Grant Applications. Based on recent data, this limit will affect a relatively small number of Principal Investigators while enabling the NIH to maintain consistently high-quality grant application review and appropriately steward taxpayer dollars.

Alycia Booth,

NIH Federal Register Certifying Official,
National Institutes of Health.

[FR Doc. 2025-16218 Filed 8-22-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<https://videocast.nih.gov/watch=56978>).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: October 3, 2025.

Open: 10:00 a.m. to 1:30 p.m.

Agenda: Presentation of the NEI Director's report, discussion of NEI programs, and concept clearances.

Address: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892, Virtual Meeting.

Closed: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892, Virtual Meeting.

Contact Person: Hyo-Jung Anna Han, Ph.D., Acting Director, Division of Extramural Activities, National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892, anna.han@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice before the meeting or within 15 days after the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://www.nei.nih.gov/about/advisory-committees/national-advisory-eye-council-naec>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: August 20, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-16170 Filed 8-22-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of a meeting of the Advisory Committee on Research on Women's Health.

The meeting will be open to the public as a virtual meeting. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

Name of Committee: Advisory Committee on Research on Women's Health.

Date: October 7, 2025.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: ORWH Director's Report, NIH Inclusion Report, NHLBI's Director's Report, Opening Remarks from NIH Director, Keynote Presentation on ORWH's Role in Transforming Research Gaps into Breakthroughs, and a panel discussion to commemorate 35 years of ORWH's impact on women's health research.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Bethesda, MD 20892.

Contact Person: Lucia Hindorff, Ph.D., Health Science Administrator, Office on Research for Women's Health, Division of Program Coordination, Planning and Strategic Initiatives, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892 240-271-1509, lucia.hindorff@nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 21 days in advance of the meetings. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://orwh.od.nih.gov/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate