

**U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
Office of the Director (OD)
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)**

**Council of Councils *Ad Hoc* Meeting
December 9, 2025**

Meeting Minutes

I. CALL TO ORDER AND INTRODUCTIONS

Nicole C. Kleinstreuer, Ph.D., Acting Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the open session of the Council of Councils. The virtual meeting began at 1:30 p.m. on Tuesday, December 9, 2025. The meeting attendees are identified below. Dr. Kleinstreuer explained that the RNomics concept presented during the September 11–12, 2025, Council meeting did not achieve the required majority for approval. Council members were invited to submit feedback in advance of the December 9, 2025, Council meeting, which the concept team considered during revision.

A. Attendance

1. Council Members

Council Members Present

Chair: Nicole C. Kleinstreuer, Ph.D., Acting Director, DPCPSI, NIH

Executive Secretary: Franziska B. Grieder, D.V.M., Ph.D., Director, Office of Research Infrastructure Programs (ORIP), DPCPSI

Monica Gandhi, M.D., M.P.H., University of California, San Francisco, San Francisco, CA

Karen C. Johnston, M.D., M.Sc., University of Virginia, Charlottesville, VA

Barbara Kelley, Hearing Loss Association of America, Bethesda, MD

Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA

Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO

Kevin C. Kent Lloyd, D.V.M., Ph.D., University of California, Davis, Davis, CA

Jennifer Jaie Manly, Ph.D., Columbia University Medical Center, New York, NY

Lauren Silvis, J.D., Tempus, Inc., Washington, DC

Russell N. Van Gelder, M.D., Ph.D., University of Washington School of Medicine, Seattle, WA

Council Member Absent

Rafael Irizarry, Ph.D., Dana-Farber Cancer Institute and Harvard T.H. Chan School of Public Health, Boston, MA

2. *Ex Officio* Member Absent

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH

3. Presenters

Ian C. Nova, Ph.D., Program Director, Division of Genome Sciences, National Human Genome Research Institute (NHGRI)

Frederick R. Tyson, Ph.D., Program Director, Genes, Environment, and Health Branch, National Institute of Environmental Health Sciences (NIEHS)

Vivian Ota Wang, Ph.D., FACMG, CGC, Acting Director, OSC, DPCPSI

4. NIH Staff and Guests

In addition to Council members and presenters, others in attendance included NIH staff and interested members of the public.

B. Reminders and Procedures

Franziska B. Grieder, D.V.M., Ph.D., the Executive Secretary for the NIH Council of Councils, reviewed the following:

- Council members are Special Government Employees during the days of Council meetings and are therefore subject to the rules of conduct governing federal employees.
- Each Council member submitted a financial disclosure form and conflict-of-interest statement in compliance with federal requirements for membership on advisory councils. The financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussions of any items for which conflicts were identified.
- Time is allotted for discussion between the Council members and presenters, but time for comments from other meeting attendees is limited. The public may submit comments in writing; instructions are available in the *Federal Register* notice for the meeting, which was published on November 21, 2025.
- The minutes from this meeting will be posted on the DPCPSI website.

C. Future Meeting Dates

The next Council meetings are scheduled to be held January 29, May 14–15, and September 10–11, 2026. The January meeting will be virtual.

II. OSC REVISED CONCEPT CLEARANCE: RNOMICS PROGRAM [VOTE]

Vivian Ota Wang, Ph.D., FACMG, CGC, Acting Director, OSC, reminded attendees that the Common Fund supports uncommon approaches for catalyzing discovery, research, and solutions. Common Fund programs must be transformative and catalytic and demonstrate strong potential for research with exceptionally high and broad impact. These programs are designed to enable, accelerate, or significantly change the trajectory of research in a specific area. They focus on goal-driven outcomes and enhance the missions of multiple NIH institutes, centers, and offices to accelerate multidisciplinary research. Common Fund programs are novel and pursue innovative solutions to specific scientific challenges that no other entity is likely or able to address. Dr. Ota Wang noted that the proposed co-chairs for the program are Dr. Kyle Walsh, NIEHS Director, and Dr. Lisa Chadwick, Deputy Director of the Division of Genomic Sciences at NHGRI.

Frederick R. Tyson, Ph.D., Program Director, Genes, Environment, and Health Branch, NIEHS, reintroduced the RNomics Program, a 5-year, \$130 million dollar concept for comprehensive characterization of the RNome. Although RNA is complementary to DNA, it has not received the same level of investment in technology development and research. RNA also is much more dynamic and

diverse than DNA, and its epigenetic modification is highly complex and extremely impactful to RNA function. RNA is intimately involved in all cellular processes associated with human development and aging, as well as disease pathogenesis, and RNA-based research is a vital component of the efforts at every NIH institute and center that focuses on human health outcomes.

Dr. Tyson outlined the many complexities of RNA, including the wide variety of RNA types that are dynamically processed for specific functions, its sequence-dependent three-dimensional folding, and the large number of reversible chemical modifications RNA undergoes with broad effects. Emerging data suggest that environmental exposures can cause aberrant processes related to these modifications, leading to or resulting in a broad spectrum of diseases. The RNome encompasses all RNA molecules and their modifications expressed in a cell, tissue, or organism at a given time.

Despite significant advances in the field, current tools are not yet adequate for comprehensively characterizing the RNome. This concept aims to address impediments to advancing the state of RNA sequencing science. A 2022 report developed by the National Academies of Sciences, Engineering, and Medicine (NASEM) highlighted current limitations and articulated a comprehensive 15-year plan to move the field forward. Two areas for improvement—technology development and data standards—can be addressed within the NIH mission.

Ian C. Nova, Ph.D., Program Director, Division of Genome Sciences, NHGRI, emphasized that developing RNA sequencing technology will require pushing boundaries and supporting high-risk projects, but this concept was designed to balance those risks with the maximum chance of success. The RNomics Program is built directly in response to gaps identified in the NASEM report and aims to develop the essential toolkit of sequencing technologies and data standards needed to characterize and study the human RNome. Because RNA is highly variable, identifying a representative reference sample is impossible, so the program focuses on developing generalizable technologies that will allow the community to analyze many samples of interest. These technologies and associated data standards will act as the “connective tissue” to support increasing and accelerating the RNA science field.

The program’s first initiative focuses on technologies that can decipher the sequence of bases within RNA and the associated modifications. The NASEM report called for an investment in both improving current sequencing technologies and supporting emerging technologies. The sensitivity, specificity, and throughput of current methods are inadequate for measuring RNA with modifications. The program will support refinement and innovation through collaborative RNA sequencing technology centers that will bring together scientists with expertise in diverse fields and promote partnerships between academia and industry, expanding and strengthening existing foundations for a high chance of success. New sequencing methods with complementary and orthogonal features are needed to unravel the full complexity of RNA, and the program will build on existing NIH research by providing connection and resources to develop a suite of innovative technologies. The goal is to collect a portfolio of methods researchers can use to sequence RNA of any length or type at low concentrations regardless of modification density.

The second initiative focuses on expanding tools for functional RNA analysis. Despite significant innovation in this area, current tools are limited to small numbers of expert users. The program will promote tools that are complementary or additive to sequencing technologies, rather than reliant on them, as well as tools that are generalizable to multiple types of RNA modifications. Tools for interacting with RNA also are needed to functionally perturb RNA and its modifications to measure the outcomes. Dr. Nova noted that a smaller amount of funding is allocated to this initiative, which is important but less central.

The third initiative focuses on improving molecular RNA standards regarding modified nucleosides and long RNAs with modifications in many sequence contexts. Standards are needed to train sequencers to detect modifications accurately and to compare results from different laboratories. Dr. Nova noted that the

National Institute of Standards and Technology is interested in partnering on this initiative. Projects in the first initiative will begin by using standards from commercially available synthetic RNAs with modifications, and this initiative will eventually produce a larger set of standards with more modifications and more sequence context. Although these standards will not be ready immediately, the technologies are available and lack only infrastructure and funding to advance, so expanded standards are expected within the first year. After this, the projects and the coordinating center will perform benchmarking studies to create feedback between sequencing developers, standards producers, and the coordinating center to determine how to improve and disseminate the standards for the scientific community.

The coordinating center is the fourth initiative of the project. It will generate guidelines and data requirements for RNomics data produced within the program and for benchmarking and challenges. The coordinating center also will leverage the community to compare technologies and computational tools. The coordinating center's functions and resources will increase over the 5 years of the program, which is reflected in the funding plan. Dr. Nova pointed out that outreach will be a critical function of the coordinating center.

Dr. Nova emphasized that this program is designed to maximize the chances of success and outcomes while maintaining the high-risk, high-reward science necessary to propel technology development to the next level. By supporting emerging methods with a phased award mechanism and ensuring a strong foundation of existing methods and standards, the field is likely to flourish, and each component of the project can interact with and enhance others. Dr. Nova noted that the program will follow the milestones and dataset goals outlined in the NASEM report and that technological milestones will become centralized during the benchmarking studies conducted by the coordinating center.

This program is designed to have transformative impacts and catalytic potential for innovations across biology. Expected impacts include the creation of high-quality datasets, the generation of clinical biomarkers to diagnose and treat disease, the development of improved therapeutics based on RNA, an improved understanding of links between exposures and molecular effects, and better insight regarding RNA biology across science and human health.

Discussion Highlights

- The discussants, Drs. Kevin C. Kent Lloyd and Jennifer Jaie Manly, provided their comments. Dr. Lloyd expressed appreciation for the effort to clarify the program and noted that the presentation had resolved many of his previous concerns. He expressed support for the project. Dr. Manly added that the feasibility concerns have been addressed by the decreased interdependence among the initiatives and the increased support for emerging methods.
- Dr. Manly asked how the coordinating center will communicate with regulatory bodies in the preliminary stage. Drs. Tyson and Chadwick explained that although regulatory issues will be more relevant later in the program, NHGRI has experience with genomic technology regulations and could support early integration of regulatory considerations at the coordinating center. Dr. Nova pointed out that because one program goal is to bridge the gap between researchers developing technologies and clinicians applying them, participants from both fields can offer expertise on regulatory issues. Dr. Kleinstreuer added that there may be an opportunity to engage with such bodies as the Foundation for NIH, which coordinates public-private partnerships.
- Dr. Manly encouraged the team to provide outreach to both the scientific community and the public, especially given the current sensitivity of RNA-based technologies as a topic. Dr. Tyson affirmed that outreach would explain the main types of RNA technologies available other than

mRNA vaccines. Dr. Nova added that the program will aim to establish trust in areas in which it has been broken.

- Dr. Lloyd encouraged the team to prepare for the challenges that the program is likely to encounter and maintain nimbleness. He suggested that the program deliver a progress report to the Council several years in the future.

Vote

Dr. Grieder clarified the updated voting procedures approved at the September Council meeting, reminding attendees that a vote to approve indicates agreement with the concept as presented or with suggested modifications. A vote to disapprove reflects the Council’s opinion that the goal of the initiative should not be pursued as presented at this time. The Council may request to defer a concept; this is not a formal vote but rather a joint decision between the Council and NIH when more information or clarification is required. Members may abstain if they do not choose to register a position. A majority of Council members present is required to approve a concept.

A motion to approve the RNomics Program concept was forwarded and seconded. The motion passed with one abstention.

III. CLOSING REMARKS

Dr. Kleinstreuer expressed appreciation to the Council members for their thoughtful input and availability for the *ad hoc* meeting. She thanked Dr. Grieder in advance of her retirement and noted that transition plans for the executive secretary role would be forthcoming.

IV. ADJOURNMENT

Dr. Kleinstreuer adjourned the meeting at 3:00 p.m. EST on December 9, 2025.

V. CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Nicole C. Kleinstreuer, Ph.D.
Chair, NIH Council of Councils
Acting Director, DPCPSI, OD, NIH

Date

Franziska B. Grieder, D.V.M., Ph.D.
Executive Secretary, NIH Council of Councils
Director, ORIP, DPCPSI, OD, NIH

Date