

NATIONAL INSTITUTES OF HEALTH

OFFICE OF THE DIRECTOR

Council of Councils
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Proposed DPCPSI Reorganization

National Institutes of Health
Turning Discovery Into Health

Legislative History

- **2006:** NIH Reform Act establishes the **Division of Program Coordination, Planning, and Strategic Initiatives** (DPCPSI) within the NIH Office of the Director
- **2006:** The Act also mandated these offices be within the division: the Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, and the Office of Rare Diseases.
- **2008:** NIH organizationally created DPCPSI in the OD. In addition to the above offices, the Office of Strategic Coordination (that manages the **Common Fund**) was placed in DPCPSI.





One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and six

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

NIH Reform Act of 2006, Public Law 109-482

DPCPSI–Broad Mission Defined in Statute

DPCPSI Mission

- Identify emerging scientific opportunities, rising public health challenges, or scientific knowledge gaps across NIH.
- Coordinate NIH-wide planning, evaluation, analysis, and strategic initiatives.
- Support research that benefits from NIH-wide collaboration.

The NIH Director may assign additional functions to the Division in support of the above responsibilities as determined appropriate by the Director.

DPCPSI: NIH-wide Research Program Coordination

- While the research foci of each program office differs, they have a shared common mission to identify, coordinate, manage, and lead NIH-wide research activities working with the ICs
- The resource offices provide support to the ICs and NIH in planning, evaluation, reporting, and portfolio analysis, and administrative support to DPCPSI

DPCPSI Offices

All of Us Research Program Office*

Environmental influences on Child Health Outcomes Program Office

Office of Administrative Management

Office of AIDS Research

Office of Behavioral and Social Sciences Research

Office of Data Science Strategy

Office of Dietary Supplements

Office of Disease Prevention

Office of Evaluation, Performance, and Reporting

Office of Nutrition Research

Office of Portfolio Analysis

Office of Research Infrastructure Programs*

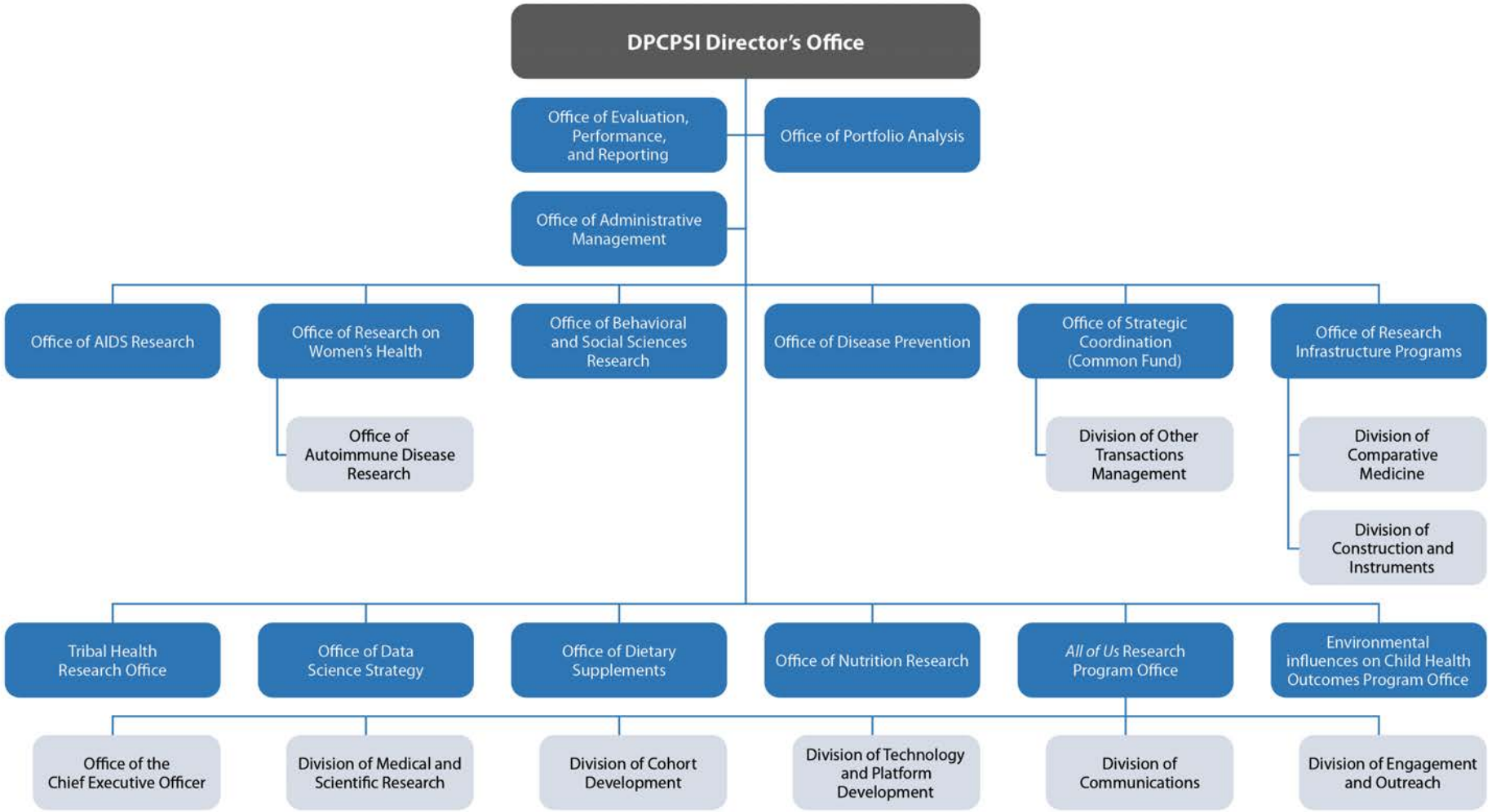
Office of Research on Women's Health*

Office of Strategic Coordination* (The Common Fund)

Tribal Health Research Office

*Contain sub-offices

Current DPCPSI Organizational Structure



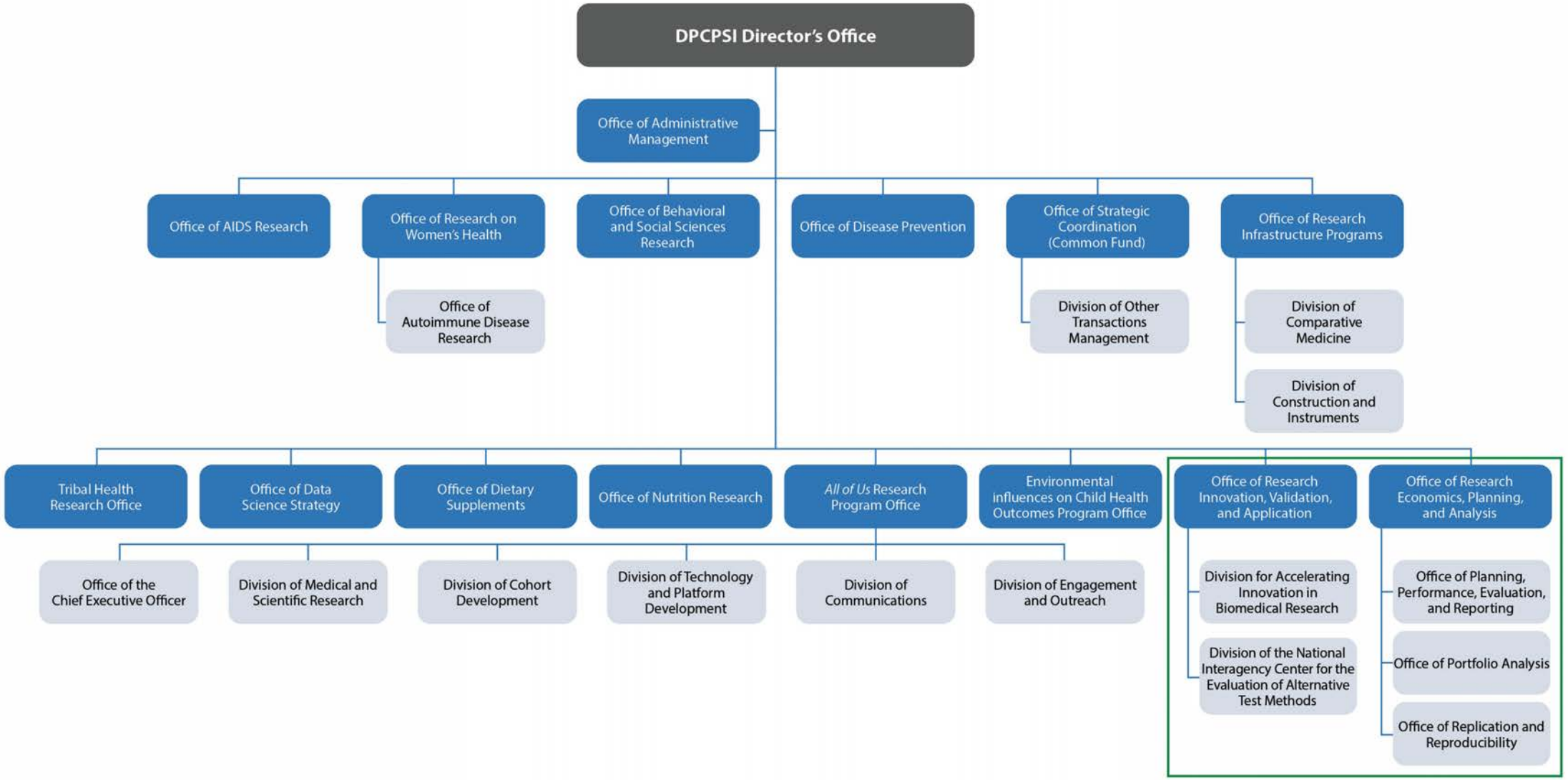
Proposed Change

- Per the NIH Reform Act, the NIH Director may assign additional functions to the Division in support of its mission and responsibilities.
- **NIH priority:** new approach methodologies (NAMs), metascience, replication and reproducibility.

The proposed reorganization would entail:

- Establishing the Office of Research Innovation, Validation, and Application (ORIVA) and its two divisions:
  - Division for Accelerating Innovation in Biomedical Research
  - Division of the National Interagency Center for the Evaluation of Alternative Test Methods
- Establishing the Office of Research Economics, Planning, and Analysis (OREPA)
  - Move the Office of Planning, Performance, Evaluation, and Reporting [formerly OEPR] under OREPA
  - Move the Office of Portfolio Analysis under OREPA
  - Establish a new Office of Replication and Reproducibility

Proposed DPCPSI Organizational Structure



Expected Benefits

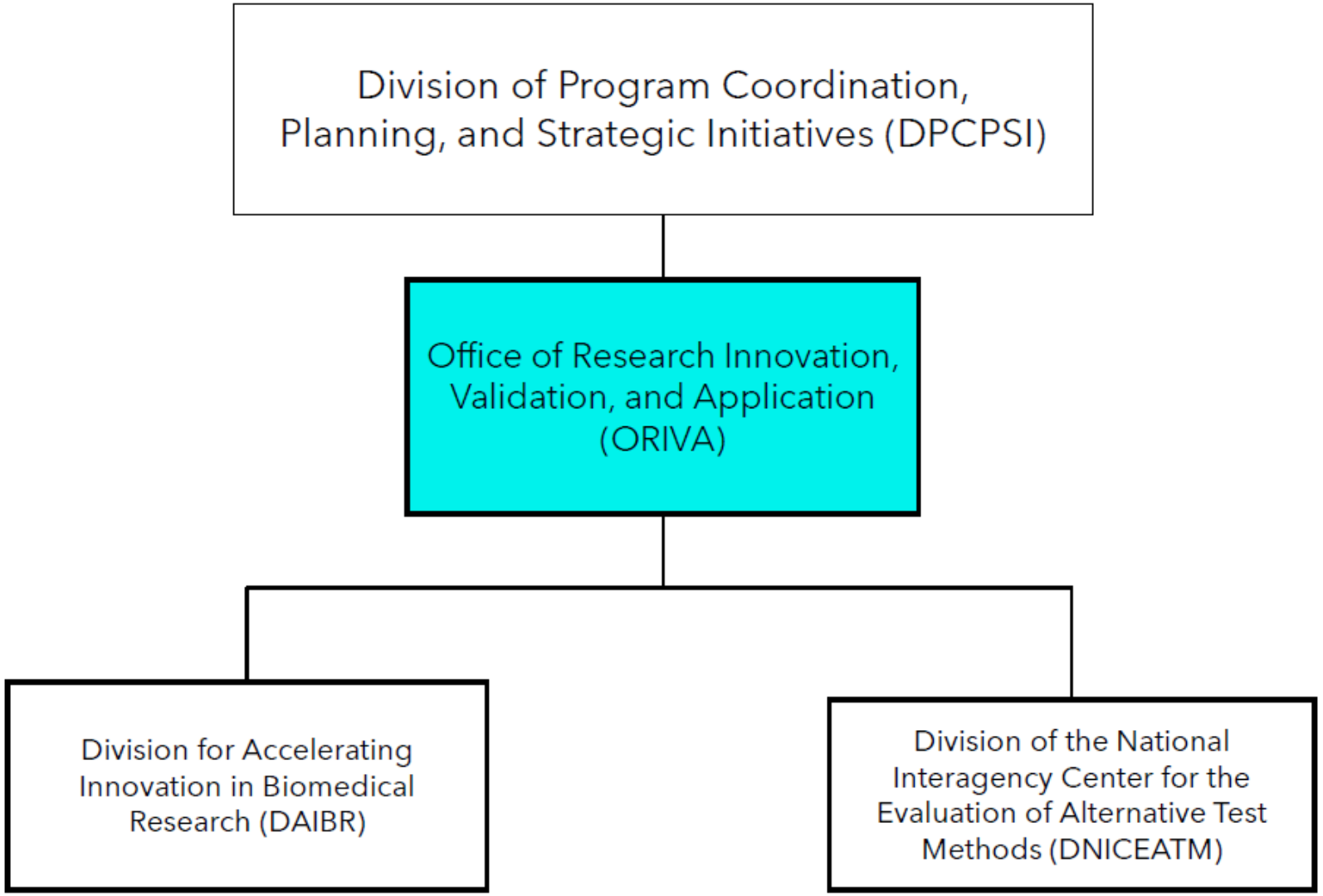
Strengthened Coordination and Research Impact

- Central NIH hub for innovation and validation of new approach methodologies.
- Stronger strategic planning, evaluation, and reporting across NIH.
- Enhanced portfolio analysis capacity and infrastructure for metascience and health economics programs.
- Enhanced coordination of replication and reproducibility and maximizing research impact.

Office of Research Innovation, Validation, and Application (ORIVA)

- Coordinate NIH-wide efforts to **develop, validate, and scale** the use of **non-animal approaches** across the NIH biomedical research enterprise.
- Serve as hub for **interagency coordination** and **regulatory translation**.
- **Strengthen integration** with NIH-wide initiatives related to scientific innovation, alternative test methods, reproducible research, and regulatory translation; and **bolster NIH's commitment** to advancing scientifically valid alternatives to animal testing.

ORIVA: Organizational Structure



ORIVA: Division for Accelerating Innovation in Biomedical Research (DAIBR)

- Supports a program of extramural research directed to the **development of alternatives** to the use of, and need for, animal models with the broad goal of **advancing human-centered research** across NIH while protecting and promoting public health.
- Fulfills a critical part of the biomedical research continuum, serving to **develop and apply new approach methodologies** (NAMs) that build the bridge between innovative basic science and human medicine.
- DAIBR will fulfill a unique need at NIH to **support research** and **research training** in these areas.

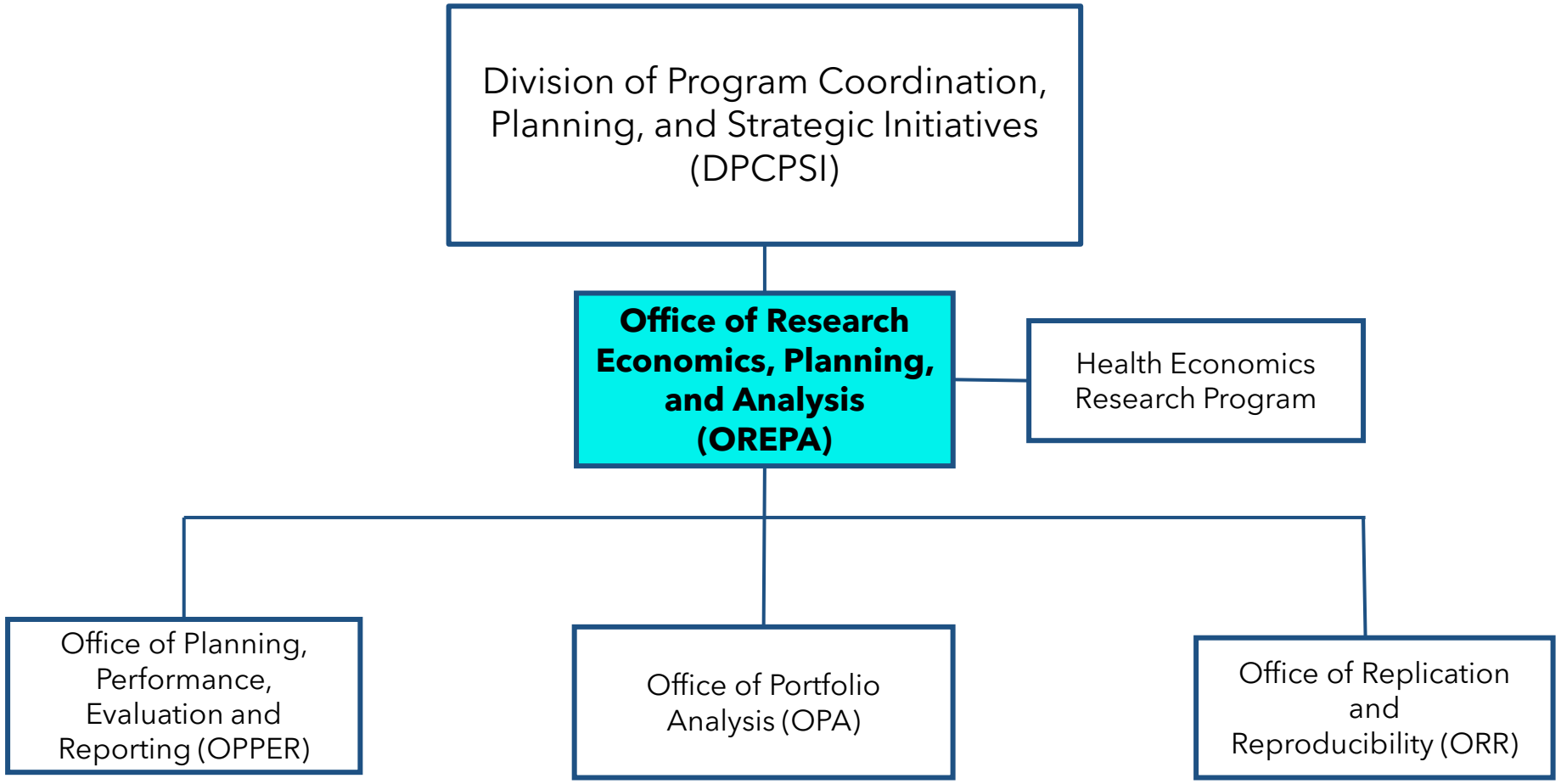
ORIVA: Division of the National Interagency Center for the Evaluation of Alternative Test Methods (NICEATM)

- A **coordinating hub** for interagency and international efforts to advance the development, evaluation, and uptake of NAMs in regulatory testing of drugs and chemicals.
- **Develop, evaluate, and promote** the use of NAMs in biomedical research.
- **Support NAMs-related activities** with relevant national and international organizations, including the:
  - Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
  - International Cooperation on Alternative Test Methods (ICATM)
  - Organization for Economic Cooperation and Development (OECD)
  - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Office of Research Economics, Planning, and Analysis (OREPA)

- Foster the development of NIH-wide **strategies for metascience**, including pilot projects and seeking input from extramural and intramural researchers.
- Encourage mission-relevant extramural **health economics research** and the integration of economic impact analysis at NIH.
- Lead NIH r**eplication and reproducibility efforts**, including supporting replication studies, educating the research community to promote culture change, and facilitating a mechanism for posting negative results.
- Coordinate and lead NIH **planning and evaluation, performance, and reporting** activities.
- Conduct innovative **portfolio analyses** and **develop new tools** and approaches.

OREPA: Organizational Structure



OREPA: Office of the Director

- Develop high-quality internal and external **infrastructure** that provides the foundation for research that advances defined NIH priorities in metascience and health economics research.
- Foster an environment where NIH-relevant health economics can flourish by **removing barriers** to innovation.
- **Promote NIH** as the premier funder of high-impact health economics research.
- Transparently **track and report** on progress toward objectives and program impact.

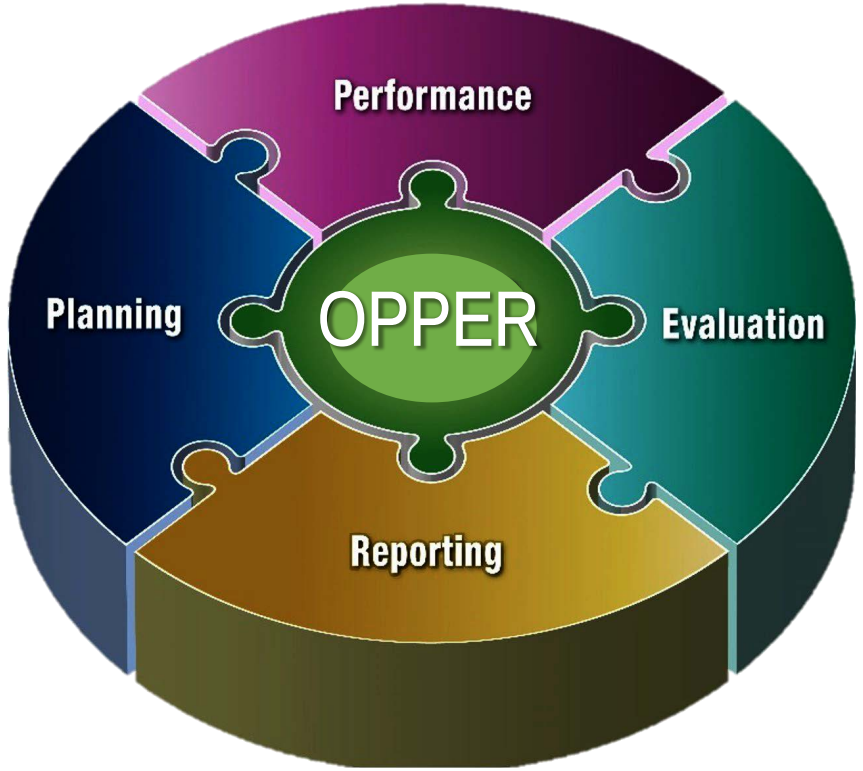
Health Economics Research Program Mission: solving health and healthcare challenges by removing barriers to economic innovation

OREPA: Office of Planning, Performance, Evaluation, & Reporting (OPPER)

Mission: To capture, communicate, and enhance the value of NIH research through stewardship activities including strategic planning, performance monitoring, evaluation, and reporting.

OPPER works across NIH to:

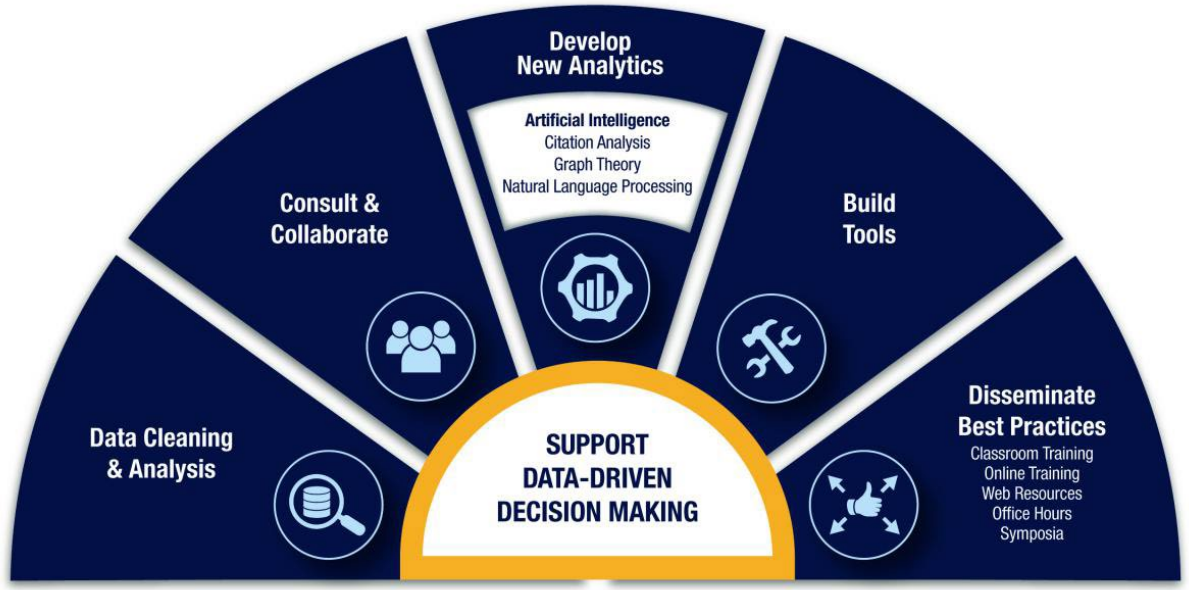
- **Strengthen strategic planning** practices and identify approaches for **better monitoring** progress toward NIH priorities.
- Increase NIH's capacity to **assess programs, policies, and operations** designed to address those priorities.
- Strengthen **communication of NIH's value**, providing transparency and accountability to the public.



OREPA: Office of Portfolio Analysis (OPA)

Overarching Goal: To accelerate biomedical research by providing access to improved methods of data-driven decision making.

- **Objective 1:** Improve the ability of decision makers to use data and tools that can help to optimize investments in biomedical research.
- **Objective 2:** Develop and disseminate metrics and standards of the highest quality that can inform best practice in portfolio analysis at NIH.
- **Objective 3:** Develop and disseminate standards of the highest quality across the metascience subfield that focuses on the biomedical research enterprise.



OREPA: Office of Replication and Reproducibility (ORR)

- **Coordinate replication and reproducibility** efforts across the Institutes, Centers, and Offices (ICOs).
- **Transform biomedical research reproducibility** through developing innovative funding mechanisms, facilitating technological innovation, and encouraging institutional culture change.
- Develop approaches that combine systematic replication studies, develop and validate an automated fraud detection system, and **coordinate and support metascience research infrastructure**.
- Develop and encourage uptake in the scientific community of **quantitative benchmarks**, including replication success rates, methodological transparency scores, and fraud detection efficiency.
- Maintain a **replication study repository** including a resource for posting negative research results.
- Collaborate with the ICOs in the **development of training grants** to build the field of replication and reproducibility.

OREPA Offices serve as a central resource

OPPER

- Strategic planning
- Performance monitoring
- Evaluation, metascience, and other assessments
- Reporting on NIH activities, impact, and value

OPA

- Quantitative analysis and application of data science methodology to the NIH portfolio
- Future engagement with Health Economics Research Initiatives

ORR

- Coordinating replication and reproducibility efforts across ICOs
- Systematic replication studies, advanced integrity systems, and metascience infrastructure
- Establish quantitative benchmarks
- Replication study repository including system for publishing negative results

HEALTH ECONOMICS

Proposed DPCPSI Organizational Structure Changes

- Establish ORIVA and its two divisions:
  - Division for Accelerating Innovation in Biomedical Research (DAIBR)
  - Division of the National Interagency Center for the Evaluation of Alternative Test Methods (DNICEATM)
- Establish OREPA and its three offices:
  - Move OPA and OPPER (formerly OEPR) under OREPA – both offices are already established within DPCPSI
  - Office of Replication and Reproducibility (ORR) to sit in line with OPA and OPPER
- HHS Secretary approval is required—we hope the proposed transfer can be effective by spring 2026
- Request for public comments posted in the Federal Register and the DPCPSI website: https://dpcpsi.nih.gov/proposed-reorg-establish-oriva-orepa

Questions?

Thank You!