



National Institutes of Health  
*Office of Autoimmune Disease Research*  
*Office of Research on Women's Health*

# **Report of the Office of Autoimmune Disease Research in the Office of Research on Women's Health (OADR-ORWH)**

**Fiscal Years 2023–2024**

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# Preface

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Autoimmune diseases encompass a diverse array of diseases that can affect nearly any part of the body and can manifest throughout the life course. Although many of these diseases are chronic, they can present acutely and may pose significant risks to organ function and overall health. Autoimmune diseases are estimated to affect 7% to 8% of the United States population, with more than 23.5 million Americans living with autoimmune diseases.<sup>1,2</sup> In recent years, autoimmune disease prevalence has been shown to be increasing,<sup>3</sup> and the growing recognition of the complexity and profound impact of these conditions underscores the need for innovative research and effective treatment strategies.

Although genetic predisposition plays a role in the development of autoimmune diseases, it cannot fully account for the rising incidence rates. It is widely accepted that various environmental exposures and triggers throughout an individual's life contribute to the onset of autoimmunity.<sup>4</sup> This area of study, known as exposome research, is critical for understanding the multifaceted nature of autoimmune diseases.

Because of their breadth and complexity, autoimmune disease research intersects with the mission of every National Institutes of Health (NIH) Institute and Center (IC). Significant strides have been, and continue to be, made across NIH ICs to advance our understanding of autoimmune disease mechanisms, identify novel therapeutic approaches, and support the implementation of these discoveries at the bedside. However, significant gaps remain, and consistent, sustained funding is needed to support autoimmune disease research.

The newly established Office of Autoimmune Disease Research (OADR) in the Office of Research on Women's Health (ORWH) is committed to fostering collaboration and support across all ICs to enhance autoimmune disease research. OADR-ORWH will build upon the existing efforts supported across autoimmune disease research at NIH with a tailored focus on identifying areas of innovation and addressing gaps within the autoimmune disease research portfolio. By targeting these gaps, OADR-ORWH aims to enhance the effectiveness of interdisciplinary research initiatives and promote strategic partnerships across NIH.

It is an exciting time in autoimmune disease research. Collaborative efforts among scientists, clinicians, and patient advocates are accelerating discoveries and improving patient outcomes. Moving forward, the integration of multidisciplinary approaches will be key in addressing the complexities of autoimmune diseases, leading to more effective interventions and potential cures.

This report encapsulates the achievements of OADR-ORWH in Fiscal Year (FY) 2023 and 2024, highlighting progress made toward fulfilling the congressional directives set forth with its establishment.

# Introduction

## Enhancing NIH Research on Autoimmune Disease

The National Academies of Sciences, Engineering, and Medicine (NASEM) published its consensus study report, *Enhancing NIH Research on Autoimmune Disease*, in 2022. In this report, NASEM evaluated the state of NIH-funded autoimmune disease research. The report acknowledged the substantial progress made by NIH in autoimmune disease research but identifies the absence of a unified, strategic approach across NIH Institutes, Centers, and Offices (ICOs). To address this gap, the report suggested establishing an Office of Autoimmune Disease/Autoimmunity Research within the Office of the Director (OD) at the NIH. The NASEM report envisioned that this new office would facilitate NIH-wide collaboration by serving as a hub for coordinating research activities across ICOs and aligning research priorities for future initiatives, underscoring the importance of cross-Institute coordination to optimize research opportunities, and enhancing the overall impact of NIH's efforts in autoimmune disease research.

The NASEM report highlighted three additional opportunities for enhancing autoimmune disease research at NIH (Figure 1, Appendix B) outlining key areas of the autoimmune disease research agenda where further support and understanding is needed to address the growing prevalence of autoimmune diseases which affect millions of people in the United States.



**Figure 1.** The NASEM 2022 consensus study report, *Enhancing NIH Research on Autoimmune Disease*, presented four opportunities for NIH to leverage for enhancing autoimmune disease research.

## Progress and Potential for Autoimmune Disease Research at NIH

NIH's investment in autoimmune disease research increased from \$800 million in FY18 to more than \$1 billion in FY22.<sup>5</sup> In FY21 and FY22, 1,425 new research and administrative supplement grants listed "autoimmune disease" as the NIH Spending Category.<sup>5</sup> This increased investment in autoimmune disease research has led to significant advancements in our understanding of and approaches to these complex conditions. Efforts across each IC have helped to accelerate scientific discovery for autoimmune diseases as well as build and maintain research capacity through the development of collaborative research networks and centers, prioritization of data utilization and advanced computational analysis, and support for the development of the biomedical research workforce. However, there are still critical gaps and opportunities that will benefit from strategic collaboration across ICs. By focusing on these gaps, NIH can leverage existing knowledge and resources to drive innovation, understanding, and collaboration in the pursuit of effective treatments and improvement of quality of life for the many individuals living with autoimmune diseases.

## The Office of Autoimmune Disease Research

The Consolidated Appropriations Act, 2023 ([Public Law 117-328](#)) provided NIH with funds to establish OADR-ORWH and enhance coordination across NIH autoimmune disease research efforts. During the [58th meeting of the Advisory Committee on Research on Women's Health \(ACRWH\)](#) on April 12, 2023, NIH Associate Director for Research on Women's Health and Director of ORWH, Janine Austin Clayton, M.D., FARVO, announced the establishment of OADR-ORWH. The mission of OADR-ORWH is to support high-priority autoimmune disease research, identify emerging areas of innovation, and foster collaboration across NIH ICOs.

OADR-ORWH formed the Coordinating Committee for Autoimmune Disease Research (CCADR), which is comprised of committee members nominated by their respective ICO directors ([see page 5 for list of members](#)). The CCADR convenes quarterly to discuss shared scientific, programmatic, and operational interests relevant to autoimmune disease research. Members of the CCADR have also collaborated extensively in the development of the inaugural *NIH-Wide Strategic Plan for Autoimmune Disease Research*.

## OADR-ORWH Team

The OADR-ORWH Director, Victoria Shanmugam, MBBS, MRCP, FACR, CCD, is an experienced physician-scientist, rheumatologist, and academic leader and has provided instrumental strategic and programmatic leadership to OADR-ORWH, enabling significant progress in addressing the congressional directives of the office and beyond.

### Directives of the Consolidated Appropriations Act, 2023

In addition to mandating the establishment of OADR-ORWH at NIH, Congress included six directives for the new office to address:

1. Coordinate the development of a multi-IC strategic research plan with concrete, meaningful milestones to set priorities
2. Identify emerging areas of innovation and research opportunity
3. Coordinate and foster collaborative research across ICs
4. Annually evaluate the autoimmune disease research portfolio to determine progress made across NIH
5. Provide resources to support planning, collaboration, and innovation
6. Develop and oversee a publicly accessible central repository for autoimmune disease research

Dr. Shanmugam expanded OADR-ORWH’s capabilities by recruiting two program officers, Carmen Ufret-Vincenty, Ph.D., in July 2024 and Xinrui Li, Ph.D., in September 2024. Collectively, OADR-ORWH has built upon the foundational work from FY23 to launch activities in FY24, placing greater emphasis on actionable and impactful initiatives aligned with the congressional directives.



**Victoria Shanmugam, MBBS, MRCP, FACR, CCD**

*Director of OADR-ORWH*

Dr. Shanmugam graduated from Oxford University with a B.A. in physiology and completed her medical degree at Imperial College School of Medicine in London, graduating with honors in medicine. She is a member of the Royal College of Physicians in London. Dr. Shanmugam completed the Internal Medicine Residency and Rheumatology Fellowship at Georgetown University and joined the faculty of Georgetown University School of Medicine in 2007. She later served as Director of Rheumatology at the George Washington University from 2014 to 2021.



**Carmen Ufret-Vincenty, Ph.D.**

*Program Officer*

Dr. Ufret-Vincenty earned a Ph.D. in biochemistry and molecular biology from the University of Maryland Medical School in Baltimore and embarked on research projects encompassing a range of disciplines, completing postdoctoral training in the Department of Physiology and Biophysics at the University of Washington. Her expertise lies in biospecimen database management, data harmonization, and clinical and translational research.



**Xinrui Li, Ph.D.**

*Program Officer*

Dr. Li obtained her Ph.D. in cell biology from the University of Alabama at Birmingham, where she also completed postdoctoral training before joining the Division of Clinical Immunology and Rheumatology as an Instructor of Medicine. Her research background and expertise include genetic and epigenetic factors associated with autoimmune diseases, as well as how these factors impact biological outcomes.

OADR-ORWH is also supported by a dedicated team of consultants from Booz Allen Hamilton—Jacqueline Robinson-Hamm, Ph.D., Lauren Roth, M.P.H., PMP, and Shanon Smith, M.P.H.—each bringing a wealth of expertise in program management, data science, and community engagement. Their diverse backgrounds and knowledge have been instrumental in supporting OADR-ORWH’s progress toward each of the congressional directives.



# NIH Coordinating Committee for Autoimmune Disease Research Membership

The CCADR is an internal NIH committee established to coordinate cross-ICO collaborations in support of autoimmune disease research at NIH. The CCADR discusses programmatic, scientific, and operational focus areas as well as action plans to leverage ongoing NIH investments in autoimmune disease research. The CCADR is composed of program staff nominated by ICO directors, OADR and ORWH leadership, and program management staff. ICO appointees represent a broad diversity of subject matter expertise and experience in autoimmune disease research, priorities, and policy. The primary representatives of the CCADR at the end of FY24 are presented below:



**Janine A. Clayton, M.D., FARVO**  
Co-Chairperson  
Associate Director for Research on Women's Health  
Director  
Office of Research on Women's Health



**Victoria Shanmugam, MBBS, MRCP, FACR, CCD**  
Co-Chairperson  
Director  
Office of Autoimmune Disease Research in the Office of Research on Women's Health



**Nandini Arunkumar, Ph.D.**  
Program Director  
Office of Strategic Development and Partnerships  
Division of Neuroscience  
National Institute on Aging



**Larissa Aviles-Santa, M.D., M.P.H.**  
Director  
Division of Clinical and Health Services Research  
National Institute on Minority Health and Health Disparities



**Preethi Chander, Ph.D.**  
Director  
Salivary Biology and Immunology Program  
Division of Extramural Research  
National Institute of Dental and Craniofacial Research



**Elaine Collier, M.D.**  
Senior Advisor to the Director  
Office of Translational Medicine  
National Center for Advancing Translational Sciences



**Tuba Fehr, Ph.D.**  
Program Director  
Division of Discovery Science and Technology (Bioengineering)  
National Institute of Biomedical Imaging and Bioengineering



**Stacy Ferguson, Ph.D.**  
Chief  
Autoimmune and Primary Immunodeficiency Diseases Section  
National Institute of Allergy and Infectious Diseases



**Nataliya Gordiyenko, Ph.D.**  
Program Director  
Angiogenesis and Immunology  
National Eye Institute



**Dan Kastner, M.D., Ph.D.**  
NIH Distinguished Investigator, Medical Genetics Branch  
Head, Inflammatory Disease Section  
National Human Genome Research Institute





**Hye-Sook Kim, Ph.D.**

Program Director  
Basic and Mechanistic Research in  
Complementary and Integrative Health  
Branch  
Division of Extramural Research  
National Center for Complementary and  
Integrative Health



**Lillian Kuo, Ph.D.**

Program Director  
Cancer Immunology, Hematology, and  
Etiology Branch  
Division of Cancer Biology  
National Cancer Institute



**Li Lin, Ph.D.**

Program Director  
Division of Metabolism and Health Effects  
National Institute on Alcohol Abuse and  
Alcoholism



**Lisa Rider, M.D.**

Head and Senior Clinician  
Environmental Autoimmunity Group  
National Institute of Environmental Health  
Sciences



**Sergio D. Rosenzweig, M.D., Ph.D.**

Chief, Immunology Service  
Senior Investigator, Department of Laboratory  
Medicine  
NIH Clinical Center



**Richard Scheuermann, Ph.D.**

Scientific Director  
National Library of Medicine



**Susana A. Serrate-Sztejn, M.D.**

Associate Director for Strategic Initiatives  
Office of the Director  
National Institute of Arthritis and  
Musculoskeletal and Skin Diseases



**Ross Shonat, Ph.D.**

Director  
Division of Physiological and Pathological  
Sciences  
Center for Scientific Review



**Lisa M. Spain, Ph.D.**

Program Director  
Division of Diabetes, Endocrinology, &  
Metabolic Diseases  
National Institute of Diabetes and Digestive  
and Kidney Diseases



**Candace Tinggen, Ph.D.**

Chief  
Gynecologic Health and Disease Branch  
Division of Extramural Research  
*Eunice Kennedy Shriver* National Institute of  
Child Health and Human Development



**Leonardo Tonelli, Ph.D.**

Chief  
Neuroendocrinology and Neuroimmunology  
Program  
Molecular and Cellular Neuroscience Research  
Branch  
Division of Neuroscience and Basic Behavioral  
Science  
National Institute of Mental Health



**Ursula Utz, Ph.D., M.B.A.**

Program Director  
Neutral Environment Cluster  
Division of Neuroscience  
National Institute of Neurological Disorders  
and Stroke



**Louis Vuga, M.D., M.P.H., Ph.D.**

Program Director  
Granulomatous and Interstitial Lung Disease  
Program  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute



**Bracie Watson, Ph.D.**

Hearing and Balance  
Division of Scientific Programs  
National Institute on Deafness and Other  
Communication Disorders

# NIH-Wide Strategic Plan for Autoimmune Disease Research

## TIMELINE OF KEY MILESTONES

**AUGUST 2023**  
**Established Working Group**  
 OADR-ORWH established a Strategic Plan Working Group (SPWG) consisting of CCADR members across ICOs to support the development of the NIH-Wide Strategic Plan

**DECEMBER 2023**  
**Published RFI**  
 OADR-ORWH requested input from members of the scientific community, federal partners, academic institutions, the private sector, health professionals, professional societies, advocacy groups, patient communities, and other interested members of the public

**FEBRUARY 2024**  
**Hosted Community Roundtables**  
 OADR-ORWH hosted two "Updates on OADR-ORWH" sessions focused on soliciting input from academic and community partners on opportunities to advance collaboration and innovation across autoimmune disease research at NIH

**APRIL 2024**  
**Conducted Portfolio Analysis**  
 OADR-ORWH curated a comprehensive autoimmune disease portfolio to include awards across more than 140 diseases and conditions. This ongoing analysis provided data-driven insights to support the development of strategic priorities and objectives

**MAY - OCTOBER 2024**  
**Drafted/Refined Priorities & Objectives**  
 In collaboration with ICO representatives, OADR-ORWH drafted and revised the strategic priorities, objectives, and crosscutting themes to meet the needs and expectations across all ICOs

**DECEMBER 2024**  
**Complete Final Draft**  
 OADR-ORWH is actively working to finalize the draft of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*, aiming for completion by December 2024

**FEBRUARY - MAY 2025**  
**Solicit NIH Review/Comment**  
 OADR-ORWH plans to circulate the full draft of the strategic plan to ICO directors and NIH leadership for comment prior to publication

**END OF FISCAL YEAR 2025**  
**Publish**  
 OADR-ORWH aims to publish and promote the *NIH-Wide Strategic Plan for Autoimmune Disease Research* by the end of FY25. Publication will be available at: <https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR>



# Congressional Directive 1: Coordinate the Development of a Multi-IC Strategic Plan

While many ICOs support autoimmune disease research in alignment with their individual mission areas, the development of an *NIH-Wide Strategic Plan for Autoimmune Disease Research* will amplify ICO efforts and advance opportunities for innovation.

To develop a comprehensive NIH-wide strategic plan, OADR-ORWH recognized the need to gather extensive input from across ICOs. As part of this effort, OADR-ORWH established a Strategic Plan Working Group (SPWG) of the CCADR, which included representatives from 22 ICOs. This collaborative approach ensured that a wide range of perspectives and expertise from across NIH would be incorporated into the strategic plan.

Moreover, OADR-ORWH’s strategic planning and priority setting process was designed to be inclusive, emphasizing the importance of contributions from the broader autoimmune disease communities. In December 2023, in coordination with the SPWG, OADR-ORWH developed and issued a Request for Information (RFI, [NOT-OD-24-029](#)) inviting input on the development of an NIH-wide strategic plan to advance autoimmune disease research. OADR-ORWH also hosted two virtual community roundtable discussions in February 2024 to garner additional insights from academic and patient advocacy partners.

Equipped with responses from the RFI and community roundtable discussions, OADR-ORWH and the SPWG convened to determine the strategic priorities, objectives, and crosscutting themes. The SPWG convened nine times in FY24 to meticulously revise and finalize the language for these strategic plan elements. These sessions were crucial in transforming broad concepts into specific, actionable, and implementable objectives and priorities. Through this iterative process, the SPWG has created a strategic plan to guide future initiatives and drive meaningful progress in the field of autoimmune disease research.

OADR-ORWH anticipates publishing the *NIH-Wide Strategic Plan for Autoimmune Disease Research* at the end of FY25, with implementation beginning in FY26.

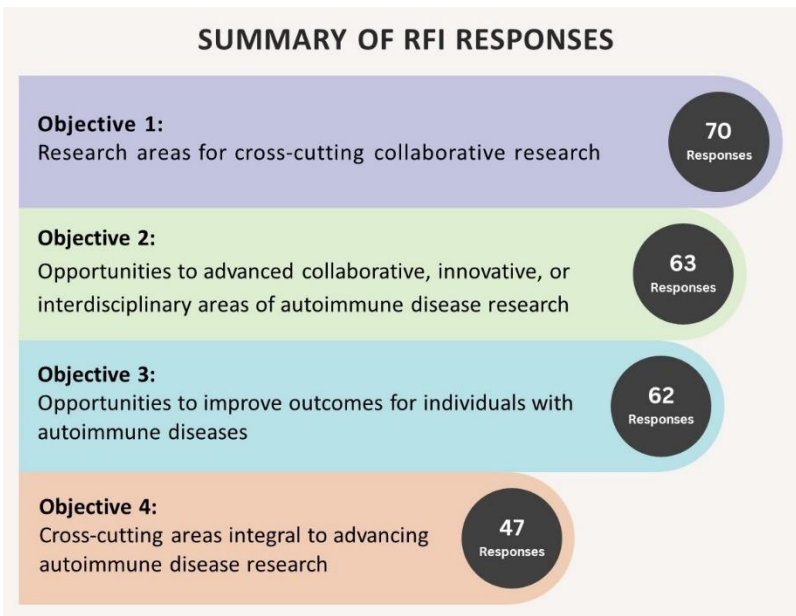
**Figure 2.** Timeline of activities supporting the development of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*. (Appendix A)

# Congressional Directive 2: Identify Emerging Areas of Innovation and Research Opportunity

Identifying emerging areas of innovation is critical to advancing autoimmune disease research. OADR-ORWH supported several initiatives in FY24 that focused on engaging the autoimmune disease community to identify key areas of innovation and research. These initiatives foster dialogue and collect valuable input on areas of critical need within the community. This input contributed to the development of the strategic plan and played an integral role in shaping new initiatives designed to catalyze innovation in autoimmune disease research.

As a key activity, OADR-ORWH issued the strategic plan RFI Inviting Input on an NIH-Wide Strategic Plan for Autoimmune Disease Research ([NOT-OD-24-029](#)), which garnered more than 75 responses. These responses were categorized into four primary objectives (see Figure 3). The RFI responses emphasized the need for innovative and cross-cutting research approaches that address the complexities surrounding prevention, diagnosis, treatment, and cure of autoimmune diseases.

To further engage the public and maintain an ongoing dialogue, OADR-ORWH initiated quarterly “Updates on OADR-ORWH” online sessions. These sessions are designed to facilitate engagement and information exchange with advocacy groups, researchers, and members of the autoimmune disease community. The inaugural sessions were hosted in [February 2024](#), followed by two additional events in [May](#) and [July](#) 2024. These “Updates on OADR-ORWH” sessions have become a cornerstone of OADR-ORWH’s efforts to keep the autoimmune disease community informed and engaged.



**Figure 3.** Four primary objectives identified through qualitative analysis of more than 75 responses to the RFI ([NOT-OD-24-029](#)).

In addition, OADR-ORWH established the quarterly ScienceTALKS series, which targets a more research-focused audience. This series aims to examine the state of science in specific areas impacting autoimmune disease research. Each session includes an open forum in which featured researchers and the audience can discuss the science and collaborate beyond conventional boundaries. The inaugural session, “[Xist-ing Data: Why Might Autoimmune Diseases Be More Common in Women?](#),” was hosted in April 2024 with an additional session, “[Going Viral: Exploring Viral Triggers of Autoimmune Diseases](#),” in August



Past and upcoming quarterly ScienceTALKS events hosted by OADR-ORWH can be found on the OADR-ORWH Events Webpage



2024. Combined these sessions received more than 1,000 total views with a global reach to more than 20 different countries. This series has proven to be a valuable platform for fostering scientific discourse and collaboration.

OADR-ORWH also engaged research and community partners at the [8th Annual Vivian W. Pinn Symposium, “Synergy in Science: Innovation in Autoimmune Disease Research and Care.”](#) This symposium brought together a diverse array of speakers to discuss the convergence of cutting-edge insights and collaborative efforts in the realm of autoimmune diseases. This event underscored the importance of interdisciplinary collaboration and integration of patient perspectives in scientific advancements.

Engagement across the autoimmune disease community is a priority for OADR-ORWH. The office participated in over a dozen public meetings and speaking engagements focused on raising awareness of the OADR-ORWH mission and the future direction of autoimmune disease research. These efforts have been instrumental in building a cohesive and informed community dedicated to advancing the field.



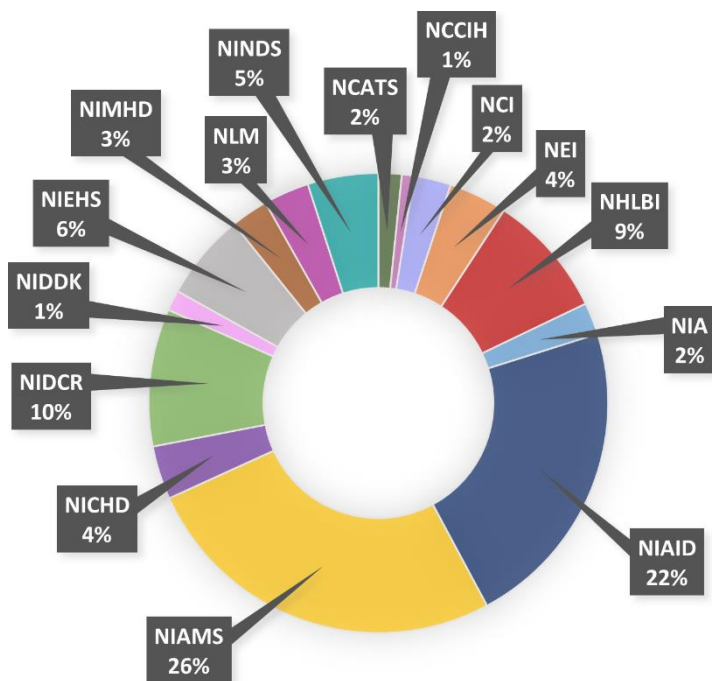
For additional resources and information related to OADR-ORWH initiatives, check out the OADR-ORWH website, <https://orwh.od.nih.gov/OADR-ORWH>

# Congressional Directive 3: Coordinate and Foster Collaborative Research Across ICs

The autoimmune disease research portfolio encompasses more than 140 different diseases and conditions, many of which intersect across multiple IC mission areas because of the systemic nature of autoimmune diseases. Central to OADR-ORWH’s mission is the facilitation of collaborative autoimmune disease research across IC mission areas. Toward this aim, OADR-ORWH’s supports new and existing research awards focused on multi-IC research initiatives and interdisciplinary research teams. In addition, OADR-ORWH actively engages with ICs to identify and address gaps within the autoimmune disease research portfolio through the issuance of Notices of Special Interest (NOSIs) and endorsement of multi-IC Notices of Funding Opportunity (NOFOs). In collaboration with the CCADR, OADR-ORWH promotes and advances multi-IC initiatives as well as identifies future opportunities for cross-IC collaboration. OADR-ORWH also engages in various joint autoimmune disease research activities including relevant workshops, consortia, working groups, and other ICO events and meeting.

## OADR-ORWH Co-Funding

OADR-ORWH supports extramural and intramural high-priority autoimmune disease research. In FY23 and FY24, OADR-ORWH co-funded 92 awards including 54 extramural research awards, 7 [R56 bridge awards](#), 18 [intramural research awards](#), 11 [intramural scientific fellowships](#), 1 workshop, and 1 contract/cooperative agreement. OADR-ORWH strategically supported research across 14 autoimmune disease areas, encompassing 52 different autoimmune diseases, as well as crosscutting research in the immunome, exposome, and data integration. These awards were distributed to 15 different ICs (Figure 4), fulfilling the OADR-ORWH objective to support autoimmune disease research across NIH and enhance resources for new and ongoing research.



**Figure 4.** Combined distribution of OADR-ORWH co-funds across 15 different NIH ICs for FY23 and FY24.

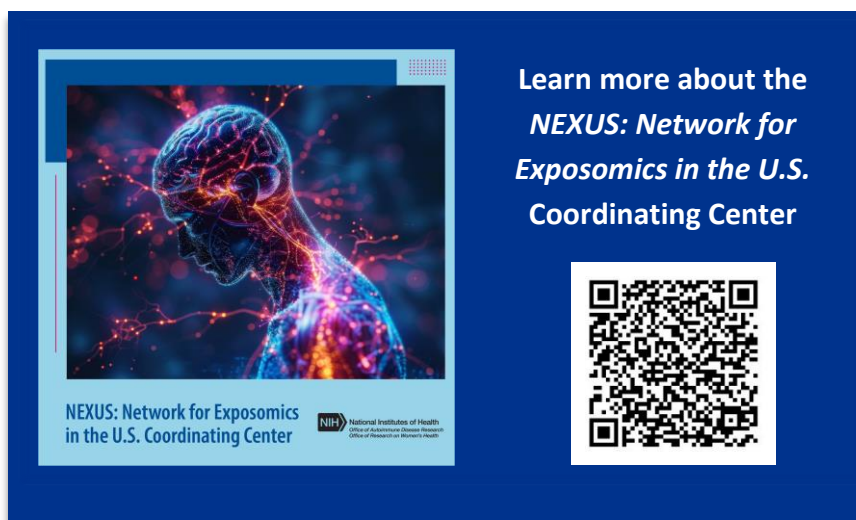
\*NCATS = National Center for Advancing Translational Sciences, NCCIH = National Center for Complementary and Integrative Health, NCI = National Cancer Institute, NEI = National Eye Institute, NHLBI = National Heart, Lung, and Blood Institute, NIA = National Institute on Aging, NIAID = National Institute of Allergy and Infectious Diseases, NIAMS = National Institute of Arthritis and Musculoskeletal and Skin Diseases, NICHD = Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIDCR = National Institute of Dental and Craniofacial Research, NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases, NIEHS = National Institute of Environmental Health Sciences, NIMHD = National Institute on Minority Health and Health Disparities, NINDS = National Institute on Neurological Disorders and Stroke, and NLM = National Library of Medicine

The EXposome in Autoimmune Disease Collaborating Teams PLANning (EXACT-PLAN) awards were the inaugural funding opportunity from OADR-ORWH and were issued and awarded in FY23 in collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Environmental Health Sciences (NIEHS), the National Eye Institute (NEI), the National Institute on Aging (NIA), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Institute of Dental and Craniofacial Research (NIDCR), and the National Center for Complementary and Integrative Health (NCCIH). The EXACT-PLAN awards focused on supporting the design, development, and implementation of a future national, interdisciplinary, collaborative, team science research network that will advance the study of the exposome in autoimmune diseases. OADR-ORWH supported six [EXACT-PLAN awards](#), which are administered in collaboration with NIAMS.

In FY23 and FY24, OADR-ORWH supported two multi-year awards from the collaborative [Accelerating Medicines Partnership® Autoimmune and Immune-Mediated Diseases \(AMP® AIM\) program](#) managed through the Foundation for the NIH, with support from NIAMS, NIDCR, NEI, the National Institute of Allergy and Infectious Diseases (NIAID), private partners, and philanthropic organizations. The AMP® AIM program is a public-private partnership that brings together the resources of the public, private, and not-for-profit sectors to pioneer a transformational approach to studying autoimmune diseases at a cellular level, with a focus on identifying potential new targets for drug development. In FY24, OADR-ORWH also co-funded an additional AMP® AIM award to support the [Technology and Analytic Cores \(TACs\) and Research Management Unit \(RMU\)](#).

In FY24, OADR-ORWH forged a new collaboration with NIAID's [Autoimmunity Centers of Excellence \(ACE\)](#) program. This partnership led to the expansion of the ACE network, which now includes a new center focused on endocrine-specific autoimmunity, along with five new pilot projects across the ACE network. The ACE program is designed to enable collaborative research in the search for effective treatments for autoimmune diseases. OADR-ORWH's support for an additional center focused on autoimmune endocrinopathies as well as the pilot projects has provided a catalyst to increase collaboration across centers and to accelerate the development of innovative therapies for autoimmune diseases.

In collaboration with NIEHS, NIAMS, NIA, the National Cancer Institute, and the National Institute of Neurological Disorders and Stroke, OADR-ORWH also supported the establishment of [NEXUS: Network for Exposomics in the U.S. Coordinating Center](#). This coordinating center aims to support the integration of exposomics across all NIH ICOs, promoting interdisciplinary partnerships that seek to better understand how environmental factors impact health outcomes including autoimmune diseases.



Learn more about the **NEXUS: Network for Exposomics in the U.S. Coordinating Center**



## Notices of Special Interest and Notices of Funding Opportunity

OADR-ORWH has leveraged several NOSIs—which highlight scientific areas of specific interest to NIH—to address research gaps within the autoimmune disease research portfolio and support high-priority crosscutting science. In FY24, in collaboration with seven ICs, OADR-ORWH issued the NOSI “R13 Support for Conferences and Scientific Meetings to Support Consensus Building for Autoimmune Disease Research Related Common Data Elements” ([NOT-OD-24-145](#)). Additionally, OADR-ORWH collaborated with the National Institute on Deafness and Other Communication Disorders to co-issue a NOSI ([NOT-DC-25-003](#)) for research to better understand autoimmune inner ear disease, also known as autoimmune-associated sudden sensorineural hearing loss, a current gap within the NIH autoimmune disease research portfolio. OADR-ORWH also collaborated with five administering ICs on the issuance of six other NOFOs relevant to autoimmune disease research in FY24.

## Collaborative Engagement Across Institutes, Centers, and Offices

OADR-ORWH fosters collaboration among ICOs in support of autoimmune disease research. In addition to chairing the CCADR, OADR-ORWH participated in several ICO-led activities in FY23 and FY24 pertaining to autoimmune disease research (Figure 5). Currently, OADR-ORWH is involved in seven working groups and consortia, contributing representation and insights to enhance autoimmune disease research across NIH. Furthermore, OADR-ORWH collaborated across ICOs on five different autoimmune-related workshops in FY24, both internal and external to NIH, serving in roles such as keynote speaker, moderator, panelist, and active participant. OADR-ORWH also participated in numerous other meetings and events across NIH with the goal to strengthen existing partnerships and promote the development of new collaborative efforts across the autoimmune disease research community.

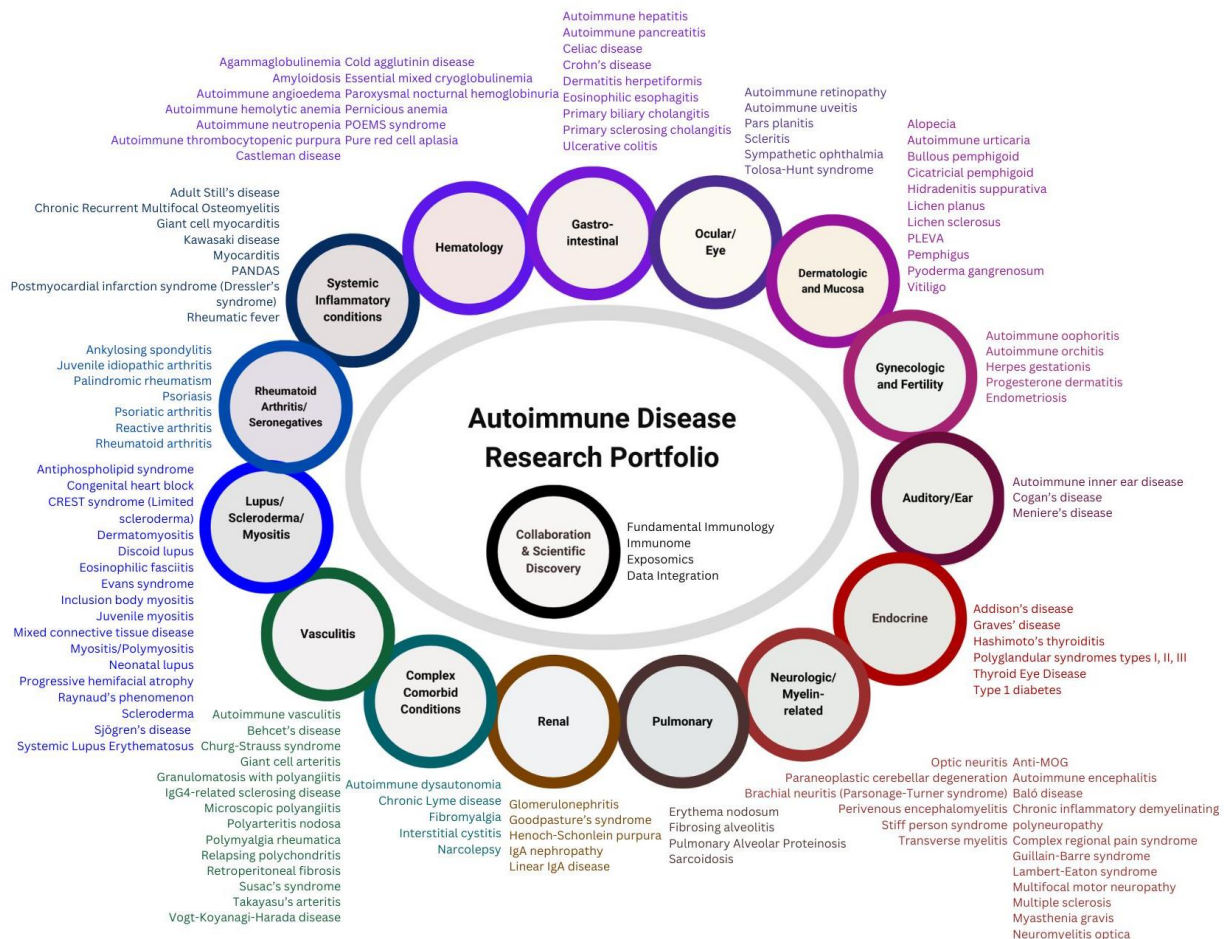


**Figure 5.** OADR-ORWH engaged in 28 activities across numerous NIH ICOs in FY23 and FY24, including consortia, working groups, workshops, and events/meetings, of which 17 included presentations and speaking engagements from OADR-ORWH leadership.

# Congressional Directive 4: Annually Evaluate the Autoimmune Research Portfolio

NIH supports a broad range of basic to clinical research on autoimmunity and autoimmune diseases. Autoimmune disease research is conducted and supported across various NIH ICOs in alignment with their mission areas.

To support the development of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*, OADR-ORWH has been conducting a baseline landscape analysis of NIH’s autoimmune disease research portfolio. For the purpose of this analysis, more than 140 diseases and conditions (Figure 6, Appendix C) listed in the NASEM report, [Enhancing NIH Research on Autoimmune Disease](#), and considered to be either autoimmune or to coexist with autoimmune diseases were reviewed. An additional crosscutting category of fundamental immunology research was included in the portfolio because understanding autoimmune diseases requires a holistic view of the immune system, which cannot be achieved without studying its fundamental mechanisms. This analysis is being used to inform the strategic plan by providing data-driven insights on gaps within the portfolio.



**Figure 6.** The autoimmune diseases portfolio encompasses more than 140 different diseases and conditions parsed out across 15 disease areas aligned by organ system and/or mechanism in addition to a crosscutting category of fundamental immunology research.

## Congressional Directive 5: Provide Resources to Support Planning, Collaboration, and Innovation

OADR-ORWH has supported several initiatives in FY23 and FY24 that exemplify its commitment to provide resources for planning, collaboration, and innovation across autoimmune disease research.

The EXACT-PLAN initiative focuses on developing foundational collaborations through exploratory projects that enable investigators to plan research strategies and develop infrastructure needed to study exposures across the lifespan that may impact the development of autoimmune diseases. The projects are also working toward the development of a research framework for autoimmune disease research as well as strategies to support coordination among studies, collaborative research projects, and sites.

Dovetailing with these efforts, in FY24 OADR-ORWH collaborated with NIEHS to co-fund the *NEXUS: Network for Exposomics in the U.S* Coordinating Center. The NEXUS Coordinating Center aims to establish a framework and best practices for exposomics analysis of biological and environmental samples, develop a framework for geospatial-based exposomics studies of environmental and social influences on health and disease, and create a comprehensive exposomics digital framework to support precision environmental health. It will also engage with multidisciplinary academic, community, and industry partners, in the U.S. and around the world, and will support bootcamps, conferences, and other learning opportunities to grow exposomics as a field, with attention to overcoming socioeconomic inequities.

In conjunction with scientists from NIAMS and NIEHS, OADR-ORWH Director Dr. Shanmugam co-authored an editorial, "[Coordination and Collaboration to Support Exposome Research in Autoimmune Diseases](#)," in *Arthritis Care & Research* that examines the critical role of the exposome in shaping current and future autoimmune disease research at NIH. Drs. Shanmugam and Clayton also co-authored a publication in *Arthritis & Rheumatology*, "[Introducing the Office of Autoimmune Disease Research](#)," that provides the autoimmune disease community with information on the vision for OADR-ORWH as well as resources for sharing input on the *NIH-Wide Strategic Plan for Autoimmune Disease Research*. OADR-ORWH is committed to identifying opportunities for synergistic innovation focused on areas of autoimmune disease research that will benefit from multi-ICO partnerships and opportunities to catalyze cross-cutting research.



On May 23, 2024, researchers and personnel supporting the EXACT-PLAN awards, including OADR-ORWH Director Dr. Shanmugam, gathered in Seattle, at the first EXACT-PLAN Summit. Summit participants learned about groundbreaking research from experts in autoimmunity and exposome science and engaged in discussions regarding approaches to integrating the exposome into autoimmune disease research.

## Congressional Directive 6: Develop and Oversee a Publicly Accessible Central Repository for Autoimmune Disease Research

Many cohorts, technical and analytic cores, and data and biospecimen repositories currently exist across NIH-funded autoimmune disease research. Developing mechanisms to facilitate analysis of distributed datasets for autoimmune disease research is a critical need, which if addressed will accelerate opportunities for discovery in the field of autoimmunity. By leveraging existing repositories within a federated data platform with integrated analytic capabilities, researchers will be able to accelerate meaningful insights that directly contribute to better diagnosis, treatment, and management of autoimmune diseases.

In FY24, OADR-ORWH partnered with the National Library of Medicine (NLM) to fund a one-year pilot of a federated data platform for autoimmune disease research to broaden analytic capabilities across a digital data ecosystem of NIH-funded research with future scalability. A federated data model offers the benefit of allowing data analysis across multiple, distributed datasets without needing to centralize the data sources—this model allows for datasets to be interrogated locally using a common query—maintaining data privacy and security while enabling large-scale, collaborative analysis. This platform enables researchers to develop analytic algorithms and identify patterns, correlations, and potential therapeutic targets more efficiently. This focused approach may accelerate the development of new treatments and interventions, ultimately improving health outcomes for individuals living with autoimmune diseases. The overall goal of this pilot project is to assess feasibility of a federated data platform for autoimmune disease research. If successful, this type of data infrastructure could serve as a platform for biomedical discovery and data-powered health, creating an epicenter for data analytics across autoimmune disease research. Through enhancing data interoperability and fostering a collaborative research environment that drives innovation, OADR-ORWH strives to advance understanding of autoimmune diseases across the lifespan.

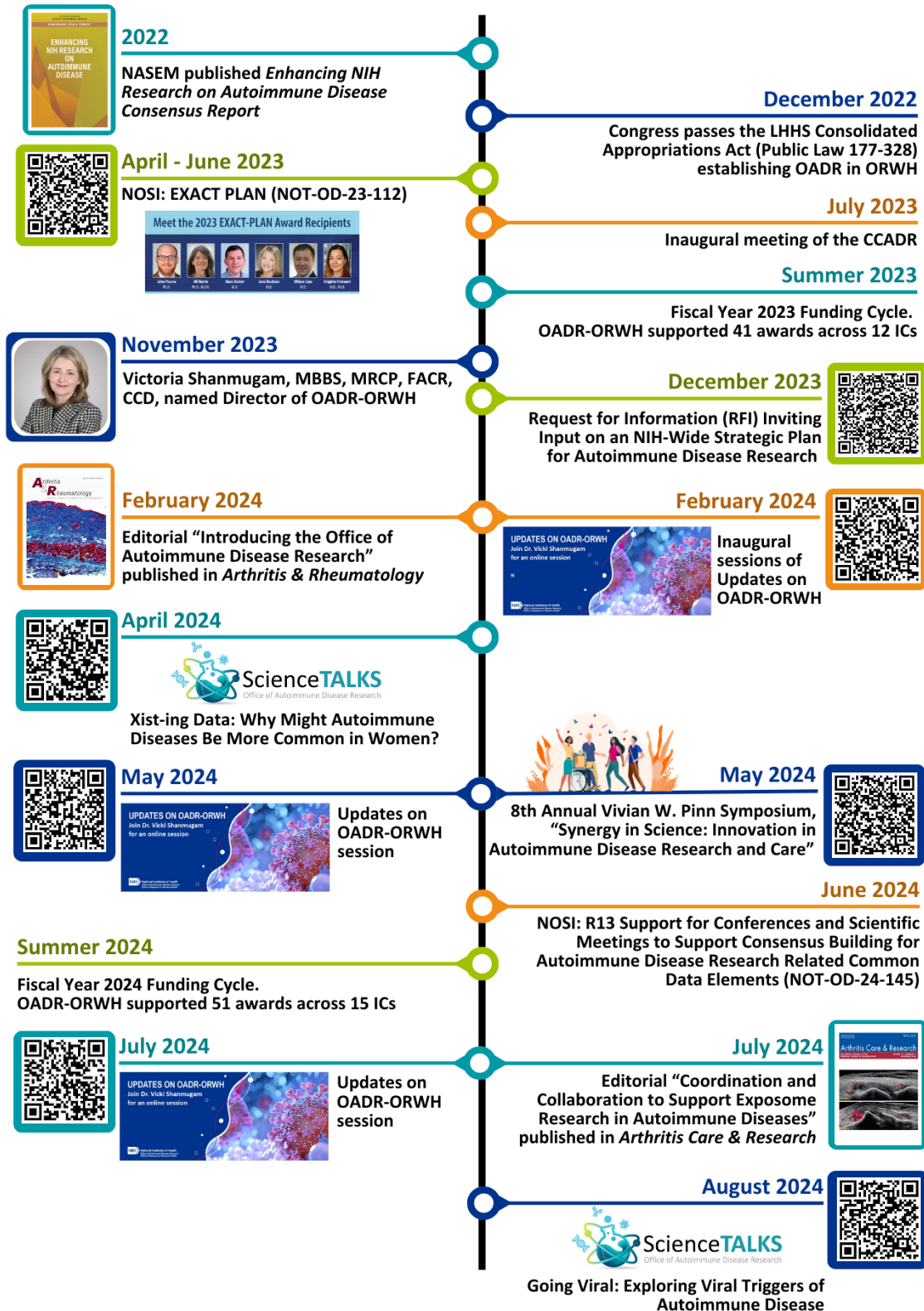
Harmonizing and enhancing interoperability of data assets is crucial to the future of autoimmune disease research. OADR-ORWH is assisting efforts across NIH to increase the number of [NIH-endorsed Common Data Elements \(CDEs\)](#) related to autoimmune disease. A CDE is a standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection. Currently, numerous CDEs are utilized by researchers in autoimmune disease research; but very few CDEs specific to autoimmune disease have been endorsed in the NIH-endorsed CDE repository. The development and endorsement of CDEs for autoimmune disease research will improve the quality of data collected in NIH-funded research, enabling comprehensive analysis across distributed datasets. To provide resources to support this effort, OADR-ORWH published a NOSI ([NOT-OD-24-145](#)) to support scientific consensus-building conferences necessary for the development of endorsed CDEs across specific areas of autoimmune disease research.

In summary, OADR-ORWH is taking a multi-pronged approach to developing resources to support autoimmune disease research repositories through leveraging novel technologies and enabling federated data models to accelerate interoperability of existing data for autoimmune disease research.



# Summary of OADR-ORWH Achievements

In summary, OADR-ORWH made significant progress toward meeting the congressional directives in FY23 and FY4 (Appendix D). To learn more about these activities, follow the QR codes below or visit <https://orwh.od.nih.gov/OADR-ORWH>.



# Appendix A: NIH-Wide Strategic Plan for Autoimmune Disease Research Timeline of Key Milestones

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## August 2023: Established Working Group

- OADR-ORWH established a Strategic Plan Working Group (SPWG) consisting of CCADR members across ICOs to support the development of the NIH-Wide Strategic Plan

## December 2023: Published RFI

- OADR-ORWH requested input from members of the scientific community, federal partners, academic institutions, the private sector, health professionals, professional societies, advocacy groups, patient communities, and other interested members of the public

## February 2024: Hosted Community Roundtables

- OADR-ORWH hosted two “Updates on OADR-ORWH” sessions focused on soliciting input from academic and community partners on opportunities to advance collaboration and innovation across autoimmune disease research at NIH

## April 2024: Conducted Portfolio Analysis

- OADR-ORWH curated a comprehensive autoimmune disease portfolio to include awards across more than 140 diseases and conditions. This ongoing analysis provided data-driven insights to support the development of strategic priorities and objectives.

## May–October 2024: Drafted/Refined Priorities and Objectives

- In collaboration with ICO representatives, OADR-ORWH drafted and revised the strategic priorities, objectives, and crosscutting themes to meet the needs and expectations across all ICOs

## December 2024: Complete Final Draft

- OADR-ORWH is actively working to finalize the draft of the *NIH-Wide Strategic Plan for Autoimmune Disease Research*, aiming for completion by December 2024

## February–May 2025: Solicit NIH Review/Comment

- OADR-ORWH plans to circulate the full draft of the strategic plan to ICO directors and NIH leadership for comment prior to publication

## End of FY25: Publish

- OADR-ORWH aims to publish and promote the *NIH-Wide Strategic Plan for Autoimmune Disease Research* in August 2025. Publication will be available at: <https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR>.



# Appendix B: National Academies of Sciences, Engineering, and Medicine Consensus Study Report, Enhancing NIH Research on Autoimmune Disease

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The NASEM 2022 consensus study report, [\*Enhancing NIH Research on Autoimmune Disease\*](#), presented four opportunities for NIH to enhance autoimmune disease research.

## Opportunity 1:

Establish an Office of Autoimmune Disease/Autoimmunity Research within the Office of the Director at the NIH.

## Opportunity 2:

Establish long-term systems to collect and ensure optimum usability of population-based surveillance and epidemiological data (e.g., incidence, prevalence) on autoimmune diseases and measures of autoimmunity (e.g., autoantibodies, inflammation) and support the optimization of existing data sources.

## Opportunity 3:

Support the development of population cohorts that extend from the period before disease manifests to the development of symptoms and disease and should support patient cohorts that will allow the examination of the progression, coexisting morbidities, and long term (20+ years) outcomes of autoimmune diseases. Data collection should include, but need not be limited to:

- Genome-wide association
- Environmental/occupational exposures
- Autoantibody, cytokine, T cell assays
- Response to therapy
- Development of co-occurring autoimmune disease

## Opportunity 4:

Provide funding and support for a national autoimmune disease research agenda that addresses key gaps identified by the committee. Prioritized research streams should include, but need not be limited to, clinical and basic research that addresses the research streams:

- Common and disease-specific pathogenic mechanisms
- Rare autoimmune diseases and animal models
- Autoantibodies and biomarkers that predict progression
- Genetic variants and gene-environment interactions
- Environmental exposures and social determinants of health across the lifespan
- Impact of coexisting morbidities and complications
- Health equity for all autoimmune disease patients
- Direct and indirect costs of autoimmune diseases

# Appendix C: Autoimmune Disease Research Portfolio

The autoimmune diseases portfolio encompasses more than 140 different diseases and conditions parsed out across 15 disease areas aligned by organ system and/or mechanism in addition to a crosscutting category of fundamental immunology research. This list of autoimmune diseases is drawn from the diseases and conditions referenced in the NASEM report, [Enhancing NIH Research on Autoimmune Disease](#).

## Auditory/Ear

|                              |
|------------------------------|
| Autoimmune inner ear disease |
| Cogan’s syndrome             |
| Meniere’s disease            |

## Complex Comorbid Conditions

|                         |
|-------------------------|
| Autoimmune dysautonomia |
| Chronic Lyme disease    |
| Fibromyalgia            |
| Interstitial cystitis   |
| Narcolepsy              |

## Dermatologic/Mucosa

|   |
|---|
| Alopecia areata                                       |
| Autoimmune urticaria                                  |
| Benign mucosal pemphigoid                             |
| Bullous pemphigoid                                    |
| Cicatricial pemphigoid                                |
| Hidradenitis suppurativa                              |
| Lichen planus   |
| Lichen sclerosus                                      |
| Pityriasis lichenoides et varioliformis acuta (PLEVA) |
| Pemphigus   |
| Pyoderma gangrenosum                                  |
| Vitiligo  |

## Endocrine

|  |
|--|
| Addison’s disease                      |
| Graves’ disease                        |
| Hashimoto’s thyroiditis                |
| Polyglandular syndromes types I,II,III |
| Thyroid eye disease                    |
| Type 1 diabetes                        |

## Gastrointestinal

|                                |
|--------------------------------|
| Autoimmune hepatitis           |
| Autoimmune pancreatitis        |
| Celiac disease                 |
| Crohn’s disease                |
| Dermatitis herpetiformis       |
| Eosinophilic esophagitis       |
| Primary biliary cholangitis    |
| Primary sclerosing cholangitis |
| Ulcerative colitis             |

## Gynecological and Fertility

|                         |
|-------------------------|
| Autoimmune oophoritis   |
| Autoimmune orchitis     |
| Herpes gestationis      |
| Progesterone dermatitis |
| Endometriosis           |

## Hematology

|                                     |
|-------------------------------------|
| Agammaglobulinemia                  |
| Amyloidosis                         |
| Autoimmune angioedema               |
| Autoimmune hemolytic anemia         |
| Autoimmune neutropenia              |
| Autoimmune thrombocytopenic purpura |
| Castleman disease                   |
| Cold agglutinin disease             |
| Essential mixed cryoglobulinemia    |
| Paroxysmal nocturnal hemoglobinuria |
| Pernicious anemia                   |
| POEMS syndrome                      |
| Pure red cell aplasia               |

## Lupus/Scleroderma/Myositis

|                                      |
|--------------------------------------|
| Antiphospholipid syndrome            |
| Congenital heart block               |
| CREST syndrome (Limited scleroderma) |
| Dermatomyositis                      |
| Discoid lupus                        |
| Eosinophilic fasciitis               |
| Evans syndrome                       |
| Inclusion body myositis              |
| Juvenile myositis                    |
| Mixed connective tissue disease      |
| Myositis/Polymyositis                |
| Neonatal lupus                       |
| Progressive hemifacial atrophy       |
| Raynaud’s phenomenon                 |
| Scleroderma                          |
| Sjögren’s disease                    |
| Systemic Lupus Erythematosus         |

## Neurologic/Myelin-related

|   |
|---|
| Anti-Myelin oligodendrocyte glycoprotein (MOG)    |
| Autoimmune encephalitis                           |
| Baló disease                                      |
| Chronic inflammatory demyelinating polyneuropathy |
| Complex regional pain syndrome                    |
| Guillain-Barre syndrome                           |
| Lambert-Eaton syndrome                            |
| Multifocal motor neuropathy                       |
| Multiple sclerosis                                |
| Myasthenia gravis                                 |
| Neuromyelitis optica                              |
| Optic neuritis                                    |
| Paraneoplastic cerebellar degeneration            |
| Brachial neuritis (Parsonage-Turner syndrome)     |
| Perivenous encephalomyelitis                      |
| Stiff person syndrome                             |
| Transverse myelitis                               |

## Ocular/Eye

|                        |
|------------------------|
| Autoimmune retinopathy |
| Autoimmune uveitis     |
| Pars planitis          |
| Scleritis              |
| Sympathetic ophthalmia |
| Tolosa-Hunt syndrome   |

## Pulmonary

|                                |
|--------------------------------|
| Erythema nodosum               |
| Fibrosing alveolitis           |
| Pulmonary Alveolar Proteinosis |
| Sarcoidosis                    |

## Rheumatoid Arthritis and Seronegatives

|                               |
|-------------------------------|
| Ankylosing spondylitis        |
| Juvenile idiopathic arthritis |
| Palindromic rheumatism        |
| Psoriasis                     |
| Psoriatic arthritis           |
| Reactive arthritis            |
| Rheumatoid arthritis          |

## Renal

|                          |
|--------------------------|
| Glomerulonephritis       |
| Goodpasture's syndrome   |
| Henoch-Schonlein purpura |
| IgA nephropathy          |
| Linear IgA disease       |

## Systemic Inflammatory Conditions

|   |
|---|
| Adult Still's disease   |
| Chronic Recurrent Multifocal Osteomyelitis  |
| Giant cell myocarditis  |
| Kawasaki disease  |
| Myocarditis   |
| Pediatric autoimmune neuropsychiatric disorders associated with streptococcus infections (PANDAS) |
| Postmyocardial infarction syndrome (Dressler's syndrome)  |
| Rheumatic fever   |

## Vasculitis

|                                  |
|----------------------------------|
| Autoimmune vasculitis            |
| Behcet's disease                 |
| Churg-Strauss syndrome           |
| Giant cell arteritis             |
| Granulomatosis with polyangiitis |
| IgG4-related sclerosing disease  |
| Microscopic polyangiitis         |
| Polyarteritis nodosa             |
| Relapsing polychondritis         |
| Polymyalgia rheumatica           |
| Retroperitoneal fibrosis         |
| Susac's syndrome                 |
| Takayasu's arteritis             |
| Vogt-Koyanagi-Harada disease     |

## Collaboration & Scientific Discovery

|                        |
|------------------------|
| Fundamental Immunology |
| Immunome               |
| Exposomics             |
| Data Integration       |

# Appendix D: Summary of OADR-ORWH Achievements

## 2022

- NASEM published [Enhancing NIH Research on Autoimmune Disease](#) consensus report

## December 2022

- Congress passes the LHHH Consolidated Appropriations Act ([Public Law 117-328](#)) establishing OADR in ORWH

## April–June 2023

- NOSI: EXACT-PLAN ([NOT-OD-23-112](#)). Learn more about the [EXACT-PLAN award recipients](#).

## July 2023

- Inaugural meeting of the CCADR

## Summer 2023

- Fiscal Year 2023 Funding Cycle. OADR-ORWH supported 41 awards across 12 ICs. Learn more about [OADR-ORWH Funding](#).

## November 2023

- Victoria Shanmugam, MBBS, MRCP, FACR, CCD, named Director of OADR-ORWH

## December 2023

- [Request for Information](#) (RFI) Inviting Input on an NIH-Wide Strategic Plan for Autoimmune Disease Research published

## February 2024

- Editorial [“Introducing the Office of Autoimmune Disease Research”](#) published in *Arthritis & Rheumatology*
- Inaugural sessions of [“Updates on OADR-ORWH”](#)

## April 2024

- Inaugural ScienceTALKS session [“Xist-ing Data: Why Might Autoimmune Diseases Be More Common in Women?”](#)

## May 2024

- May [“Updates on OADR-ORWH”](#) session
- [8th Annual Vivian W. Pinn Symposium](#), “Synergy in Science: Innovation in Autoimmune Disease Research and Care”

## June 2024

- NOSI: R13 Support for Conferences and Scientific Meetings to Support Consensus Building for Autoimmune Disease Research Related Common Data Elements ([NOT-OD-24-145](#))

## Summer 2024

- Fiscal Year 2024 Funding Cycle. OADR-ORWH supported 51 awards across 15 ICs. Learn more about [OADR-ORWH Funding](#).

## July 2024

- July [“Updates on OADR-ORWH”](#) session
- Editorial [“Coordination and Collaboration to Support Exposome Research in Autoimmune Diseases”](#) published in *Arthritis Care & Research*

## August 2024

- ScienceTALKS session [“Going Viral: Exploring Viral Triggers of Autoimmune Disease”](#)

## Appendix E: References

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