

# Policy Brief

## Prioritizing Federal Research on Autoimmune and Immune-Mediated Diseases and Conditions

### How Increased Investments Can Improve Health and Quality of Life Outcomes for Women

**A**utoimmune diseases\* are estimated to affect anywhere between [23.5 million](#) and [50 million](#) Americans, and [recent evidence](#) from the National Institutes of Health (NIH) has shown that the prevalence of autoimmune biomarkers is increasing in the United States. Globally, the rates of autoimmune diseases are rising by between [3-9 percent](#) each year.

Women represent [80 percent](#) of patients diagnosed with autoimmune diseases, though gender ratios differ among individual diseases. Sex differences also [affect autoimmune disease symptoms](#), including when they manifest and how severe they are. Further, many autoimmune diseases [affect women](#) during times of extreme stress (e.g., pregnancy) or during times of great hormonal change.

The needs within autoimmune disease research are varied and numerous. These include reaching consensus on which illnesses are autoimmune diseases, understanding the underlying mechanisms of autoimmune diseases, exploring ways to prevent or reduce autoimmunity risk factors, increasing diversity in clinical trials, closing the knowledge gap surrounding the impact of autoimmune diseases on women, improving data collection efforts surrounding autoimmune diseases and conditions, and developing new diagnostic tools and technologies that could improve health and quality of life outcomes for individuals with autoimmune diseases and conditions.

Taken together, these issues demonstrate a pressing need to make autoimmune diseases and conditions a greater national priority. Sufficiently responding to this national imperative will involve investing robust, dedicated federal funding for autoimmune research, including research on the role of biological sex in autoimmune disease, incidence, symptom severity, and outcomes.

\* Note: [Immune-mediated inflammatory diseases \(IMIDs\)](#) are diseases where the causes and mechanisms of action are not fully understood, but a malfunction of the immune system is involved. [Autoimmune diseases](#) are a subset of IMIDs and are characterized by antigen presence. For the purposes of this document, "autoimmune diseases" refers to diseases and conditions across both classifications.

#### KEY MESSAGES

- Understanding of autoimmune diseases and conditions—from the underlying mechanisms of disease to the role of viral and environmental triggers and factors that can regulate immune response—is lacking.
- While autoimmune disease research is funded across the federal government, these investments are insufficient when compared to patient and caregiver burdens in the United States.
- Women are disproportionately affected by autoimmune diseases. Despite their impact (autoimmune diseases are the [fifth-leading cause of death](#) in women under the age of 65), our understanding as to why women are more susceptible is still lacking.
- The prevalence of autoimmune diseases in the United States is rising, including in adolescents. As summarized by a [2022 NASEM report](#), "The earlier an autoimmune disease manifests, the longer an individual must live with accruing damage, increased risks of complications and other conditions, and adverse effects on quality of life."
- Robust and sustained funding for autoimmune disease research could improve our collective understanding of disease pathology and inform the development of improved diagnostic tools and new interventions.

## Federal Autoimmune Disease Research Funding

**A**utoimmune disease research—from basic and clinical to public health research—is funded by federal agencies as well as private foundations and patient advocacy organizations. Some of the key entities funding autoimmune disease research include the following:

- ▶ **National Institutes of Health (NIH).** As the largest public funder of biomedical research in the world, research into specific autoimmune diseases and conditions is primarily supported by NIH’s National Institute of Arthritis and Musculoskeletal Diseases (NIAMS) and National Institute of Allergy and Infectious Diseases (NIAID).
- ▶ **Centers for Disease Control and Prevention (CDC).** CDC funds research grants, cooperative agreements, and interventions that aim to identify and control a health problem or improve a public health program or service. For example, [CDC’s work in lupus](#) involves epidemiologic research, studies lupus interventions, and conducts pilot programs to inform lupus public health practice.
- ▶ **Department of Defense (DoD).** The DoD’s Congressionally Directed Medical Research Program (CDMRP), which funds “high impact, high risk, and high gain projects” that seek to improve health care for service members and the American public, provides funding for autoimmune research. For example, the Lupus Research Program received \$10 million in fiscal year 2023 and the Multiple Sclerosis Research Program, \$20 million.
- ▶ **Department of Veterans Affairs (VA).** The VA’s Office of Research and Development focuses on health issues that affect veterans, including autoimmune diseases and conditions. [Research from the VA](#) has shown that among veterans of Iraq and Afghanistan, those with PTSD were more likely to have autoimmune disorders, such as rheumatoid arthritis, multiple sclerosis, inflammation of the thyroid, and others.
- ▶ **Food and Drug Administration (FDA).** The FDA, including its Office of Women’s Health (OWH), fund to support FDA regulatory decision-making and advance the science of women’s health. [OWH-funded research](#) includes the studies, Sex Disparities in Autoimmune Treatment Response and A Mechanistic Study of the Capacity of Silicone to Present (Self) Antigens to the Immune System. The FDA also plays a critical role in examining autoimmune drug safety.
- ▶ **National Science Foundation (NSF).** NSF, which focuses its efforts on fundamental research in science and engineering, funds research that touches on a variety of autoimmune diseases, including type 1 diabetes, multiple sclerosis, rheumatoid arthritis, and lupus. Studies on diabetes have included exploring [new technology to monitor diet](#) and [studying therapies](#) with the potential for long-term diabetes reversal.

## Issue Overview

Research on autoimmune diseases is severely underfunded compared to patient burden. In 2021, the NIH spent [\\$1.021 billion](#) on autoimmune disease research, which affects up to 50 million Americans. For comparison, cancer research funding totaled [\\$7.632 billion](#) (with an [estimated 1.9 million](#) people in the United States being diagnosed with cancer each year, and much more affected), and HIV/AIDS research funding totaled [\\$3.1 billion](#) (there are more than [1.2 million](#) people in the United States living with HIV).

Given the growing prevalence of autoimmune diseases; their complexity and disproportionate impact on women; and the pressing need to gain a greater understanding of autoimmune diseases, including research on sex as a biological variable related to autoimmune diseases and conditions, increased investment at the federal level must be prioritized.

The need for this prioritization is getting increased attention. In response to a 2019 Congressional directive to NIH calling for an assessment of “research activities on autoimmune disease with a particular emphasis on the risk factors, diagnostic tools, barriers to diagnoses, treatments, and prospects for cure” as well as “the occurrence of multiple autoimmune diseases in individuals and the interplay of the diseases with co-morbidities,” the National Academies of Sciences, Engineering, and Medicine (NASEM) released the report, “[Enhancing NIH Research on Autoimmune Disease](#).” This 2022 report effectively [summarized](#) the challenges and needs within the autoimmune disease research space, which include, but are not limited to the following:

- ▶ There is no consensus on what characterizes an autoimmune disease;

- ▶ Epidemiologic data of the United States incidence and prevalence of autoimmune diseases in the past 10-20 years are limited, and there is a lack of population-based data;
- ▶ There is limited data on the direct and indirect costs of autoimmune diseases, including on specific autoimmune diseases, in the United States; and
- ▶ Trend data are showing an increasing incidence and/or prevalence of the autoimmune diseases examined by the NASEM Committee, including in children.

These challenges and needs were echoed by Arlene Sharpe, MD, PhD, Kolokotronis University Professor at Harvard University and Chair of the Department of Immunology at Harvard Medical School, who said in an interview with [The Harvard Gazette](#), “[Autoimmune diseases] are increasing in frequency and occurring earlier in life, and we don’t understand why... There’s tremendous need to understand the causes of these diseases and how to treat them.”

Beyond the implications of growing autoimmune disease prevalence, and particularly among certain groups, there are critical needs in research surrounding autoimmune diseases and conditions in

women. Prior to the 1990s, women were excluded from clinical trials in the United States, and there was an overreliance on male mouse models in research studies. The years of exclusion and underrepresentation has—in essence—left the nation playing “catch up,” not only in health equity but also in our overall understanding of autoimmune diseases and conditions. While progress has been made, much work remains.

According to the report [Societal Impact of Research Funding for Women’s Health in Rheumatoid Arthritis](#) (RA) from Women’s Health Access Matters, despite the disproportionate impact of RA on women (the impact on women’s life years with RA is more than six times that of men’s, and the impact of productivity gains is about six times larger for women than for men), “Within the portfolio of extramural funding for RA research from the NIH over the past five fiscal years, funding with a specific focus on women’s health research accounted for 7 percent of total funding.” This underinvestment in women’s health research leads to a lack of understanding of the biological mechanisms affecting the disease, symptom manifestation, and potential treatment options available to women with autoimmune diseases.

## Looking Ahead

The [NASEM Committee’s report](#) cautions that, despite NIH’s “extraordinary work related to autoimmune disease,” there are barriers in place that inhibit NIH’s ability to maximize outcomes of their research portfolio. These barriers include the variation found in NIH’s Institutes and Centers’ (ICs) strategic plans regarding autoimmune diseases, the absence of a research plan that spans all of NIH’s ICs, and a strategic NIH plan for autoimmune diseases. The NASEM Committee agreed that addressing these challenges and opportunities would be best done through the creation of an Office of Autoimmune Disease Research within the Office of the Director of NIH.

Heeding NASEM’s advice, the final [fiscal year 2023 spending bill](#), which was signed into law in December 2022, provided \$10 million to establish an Office of Autoimmune Disease Research (OADR) under the Office of Research on Women’s Health within NIH. The language directs OADR to coordinate the development of a multi-Institute and Center strategic research plan, identify emerging areas of innovation and research opportunities, coordinate and foster collaborative research across ICs,

annually evaluate the autoimmune research portfolio to determine progress, provide resources, and develop and oversee a publicly accessible central repository for autoimmune disease research.

“It is notable that spending on autoimmune diseases as a percentage of overall NIH obligations has remained at only 2.6 percent between 2013 and 2020. This is in marked contrast to increases seen in overall NIH obligations during the same period. In addition, the distribution of this funding for autoimmune diseases indicates that certain ICs dominate overall spending on research and training and the types of research activities funded.”

– [Enhancing NIH Research on Autoimmune Disease, NASEM](#)

The establishment of this Office, while an important step forward, must be coupled with new streams of targeted, robust investments in autoimmune disease research.

Research needs concerning autoimmune diseases are vast. In 2022, SWHR convened an interdisciplinary roundtable of policy experts, researchers, clinicians, and patient advocates. The consensus recommendation of the Working Group was that certain areas of autoimmune disease research would benefit from additional investigation, such as the role of biological sex on the development of autoimmune

diseases, symptom manifestation, and symptom severity; risk factors for autoimmune diseases and conditions across different racial and ethnic groups; and the intersection between mental health and autoimmune disease. Further details are outlined in SWHR's autoimmune policy agenda, "[Improving Outcomes for Women with Autoimmune Diseases and Conditions: A Call to Action](#)."

## Recommendations

Autoimmune disease research has the potential to not only improve our collective understanding of disease pathology, but also to inform the development of improved diagnostic tools and potential new interventions. Federal policies should:

- ▶ Prioritize autoimmune research funding across federal research entities, including but not limited to the NIH OADR, once established;
- ▶ Implement policies to meaningfully improve diversity in clinical trials to ensure that the genetic and environmental influences on disease and subsequent treatments and interventions work for everyone, regardless of sex, gender, race, or ethnicity;
- ▶ Coordinate among key agencies and stakeholders to help determine a universal definition of autoimmune diseases and conditions and establish an accessible system to allow for better tracking across systems and for enhanced capacity to monitor trend data;
- ▶ Identify opportunities across entities, such as the new Advanced Research Projects Agency for Health (ARPA-H), to prioritize research into critical women's health issues, such as autoimmune diseases and conditions.

"Autoimmune diseases have a major impact on the individuals and families they affect, as well as on our society and healthcare costs, and current projections suggest they may soon take their place among the predominant medical disorders. This necessitates that we increase the scope and scale of our efforts, and coordinate our resources and studies, to understand autoimmune disease risk factors and pathogenesis and improve our diagnostic, therapeutic, and preventive approaches, as the costs of inaction will be profound and far greater without such investments."

– Frederick W. Miller, MD, PhD, "[The Increasing Prevalence of Autoimmunity and Autoimmune Diseases: An Urgent Call to Action for Improved Understanding, Diagnosis, Treatment, and Prevention](#)," *Current Opinion in Immunology*, 2023.