

LUPUS
RESEARCH
ALLIANCE

Lupus Research Alliance (LRA)/Data Sharing Policy

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HRA Spring Members Meeting
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What is Lupus?

- ✓ Lupus is an autoimmune disease in which a person's immune system mistakenly attacks the body's own tissues.
- ✓ The exact cause of lupus is unknown. Research suggests it is **caused by a combination of genetic factors that make a person susceptible to the disease and environmental factors such as infection, sunlight, or stress that trigger the disease in susceptible individuals**
- ✓ Lupus can cause life-threatening damage to major organs such as the kidneys, lungs, heart and central nervous system.
- ✓ Nine out of ten people with lupus are women.
- ✓ **Lupus affects people of all ages, including children, but it most often strikes people when they are between the ages of 15 and 45.**
- ✓ Women are five times more likely to die from lupus than men, and African Americans are three times more likely to die from lupus than Caucasians.
- ✓ **No single test can determine whether someone has SLE and it may take several years after symptoms first appear before doctors can make a definitive diagnosis.**



LRA: Who are we?

- ❑ Largest non-governmental, non-profit funder of lupus research worldwide
- ❑ Focused on funding cutting-edge, innovative research
- ❑ Spans the research spectrum from basic to discoveries to clinical trials
- ❑ Foster diverse scientific talent, stimulates collaborations and drives discoveries
- ❑ Aims to transform treatment while advancing toward a cure

LRA funding is leading to key discoveries that are improving diagnosis and therapies while enabling researchers to find the way toward prevention and ultimately a cure for lupus.

100%
OF FUNDS

go to support
research programs

500
GRANTS

fostering scientific
breakthroughs

\$200
MILLION

in support of
cutting-edge research



LRA: What do we do?

The LRA is an organization of partnerships, bringing together the key players in the fight against lupus — our grantees, scientific advisors, the pharmaceutical industry, the U.S. government, and people with lupus.

The LRA's strategic priorities are to: 1) define human lupus heterogeneity by molecular pathology; 2) Enable patient stratification based on active disease mechanisms and 3) Facilitate global research collaborations

Key areas of focus

- Grant Mechanisms – from novel grant awards to large collaborative grants and clinical trials
- Partnerships – varied partnerships in the public and private sector
- Lupus Clinical Investigators Network managed by Lupus Therapeutics
- Emerging Science meetings



LRA Data Sharing Principle

All recipients of LRA awards must agree to this principle and must take concrete steps to facilitate availability of data and materials.

- ❑ **Committed to sharing results and accomplishments of funded projects with the general public and research community**
- ❑ **Expedited translation of research results into knowledge, products and procedures with the goal of improving human health**
- ❑ **Timely release** and sharing of final research data from LRA supported studies for use by other investigators.
 - **“Timely release and sharing”** is defined as no later than the acceptance for publication of the main findings from the final data set.

LRA recognizes that data sharing may be complicated or limited by either internal or external factors



LRA Data Sharing Policy Requirements

- ❑ **A Data Sharing Plan must be completed and approved by the LRA prior to grant activation.**

preferred format: current NIH-style Data Sharing Plan

- ❑ **Protect patients and participant's rights:** Data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

- ❑ **Data from LRA funded studies should be submitted to publicly available databases.**



LRA Data Sharing Policy in Practice

❑ **Pre-Award Stage**

- *Data Sharing & Resource Sharing stated in RFA and Award Letter*
- *Application Review – we are phasing in data sharing plans as a requirements in all applications*

❑ **Post-Award Stage**

- *Grant funds may be used towards costs related to Data Sharing requirements*
- *Review of Data Sharing plan by LRA scientific staff – both during grant activation as well as during grant progress grant review*



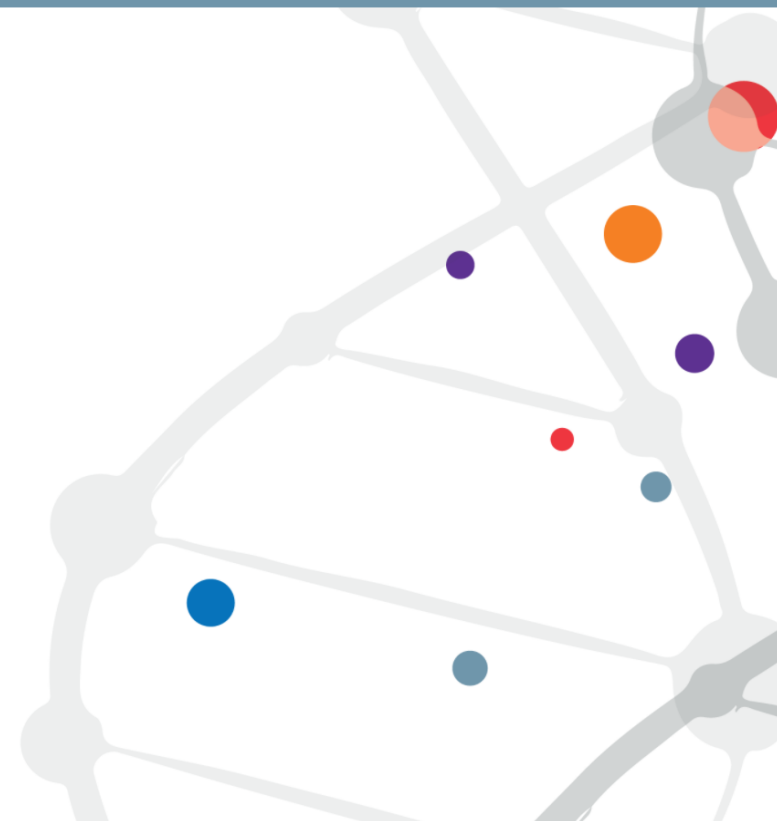
Sharing of Research Resources

LRA considers the sharing of unique Research Resources an important means to enhance the value of LRA-sponsored research. Restricting the availability of unique Research Resources can impede the advancement of further research. Therefore, **LRA requires that Research Resources developed with grant funds be made available for research purposes to the scientific community.**

- Investigators submitting grant proposals that are expected to result in the development of a Research Resource must include a plan for sharing these Research Resources or clearly explain why sharing of the Research Resource is not possible.



Currently exploring new approaches to data sharing






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Decoding Immune-Mediated Diseases

Novel Approaches for Therapeutic Insights

JDRF, Lupus Research Alliance and National Multiple Sclerosis Society have joined forces to identify common mechanisms of autoimmunity. This is the first time these three leading autoimmune disease organizations are jointly funding research projects looking at common underlying disease mechanisms.

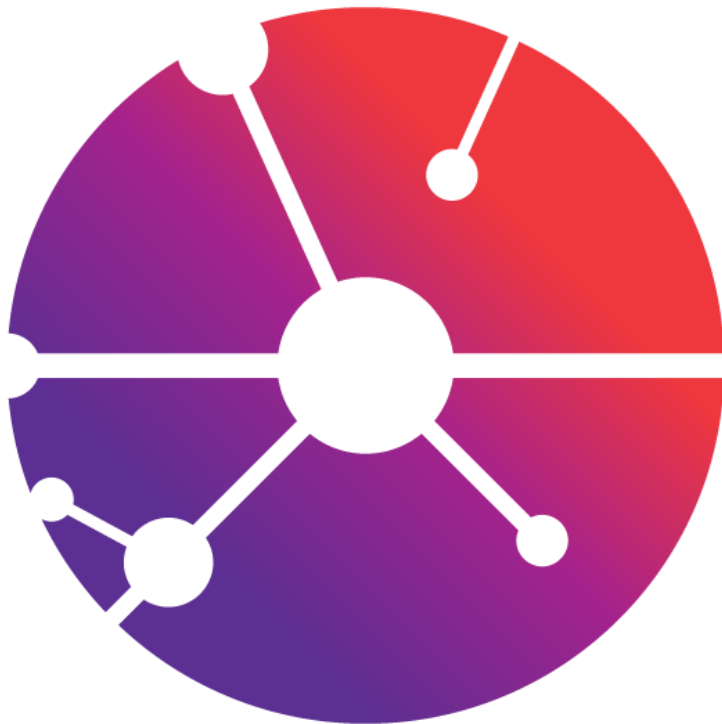
LEARN MORE

↓

Visit DecodingAutoimmunity.org for more information.



Next Steps



- ❑ Progress Reports
 - Enhanced review and follow up to ensure compliance
 - Continue incentivizing compliance
 - May penalize non-compliance
- ❑ Provide additional guidance to PIs about best practices and requirements from the LRA about how data should be shared
- ❑ Integration of data sharing into review process starting in 2022
- ❑ Developing a data strategy for the organization

www.lupusresearch.org