

## Colton Consortium for Autoimmunity

### Innovations in Monogenic Autoimmunity and Immune-Mediated Diseases RFA (FY2026)

#### Overview

Monogenic autoimmune and immune-dysregulation disorders provide an opportunity to elucidate mechanistic insights into the fundamental architecture of immune tolerance, checkpoint biology, cytokine signaling, nucleic-acid sensing, and other pathways essential to human immune function. These disorders, which include diseases caused by pathogenic variants in genes such as CTLA4, LRBA, STAT3, AIRE, DNASE1L3, TREX1, and many others, serve as powerful “natural experiments,” enabling precise causal inference that is often obscured in more complex autoimmune phenotypes. The Colton Consortium recognizes the potential of monogenic autoimmunity research to be a high-value driver of translational innovation, therapeutic development, and biomarker discovery across both rare and common immune-mediated diseases.

The purpose of this Request for Applications (RFA) is to support creation of a cross-Consortium Collaborative Research Initiative (CRI) focused on monogenic autoimmune disorders, or monogenic insights, to advance our mechanistic understanding of autoimmunity and generate translational impact. Priority will be given to proposals that discover or advance new therapeutic targets, precision medicine biomarkers, novel diagnostics, mechanistic platforms, gene- or pathway-directed therapeutic strategies, IP-generating tools, or other commercially relevant innovations. Mechanistic discovery remains central, but projects must articulate a plausible translational pathway, including potential for downstream intellectual property.

Examples of areas of potential interest for autoimmunity include but are not limited to:

- Discovery of new monogenic etiologies or pathogenic variants underlying autoimmune or other immune-dysregulatory phenotypes paired with functional validation and a translational path (e.g. new targets, biomarkers, diagnostics, etc.)
- Functional characterization of monogenic immune disorders using cellular, molecular, systems immunology, or AI-enabled approaches
- Development of therapeutic hypotheses inspired by monogenic immune pathways
- Cohort-based studies leveraging patient samples, biobanks, or high-dimensional immune profiling
- CRISPR/Cas9 or other genetic perturbation platforms, small-molecule screens, or synthetic immunology approaches to dissect monogenic pathways



- Mechanistic studies embedded in clinical trials, natural history studies, or first-in-human applications relevant to monogenic defects
- Translational platform development (e.g. diagnostics, AI models, target discovery pipelines, engineered tools, etc.) rooted in monogenic disease mechanisms

Areas considered to be non-responsive for this request include:

- Projects on autoimmune or inflammatory diseases *without* a mechanistic anchor in monogenic autoimmunity or monogenic insights
- Pure basic immunology that does not offer translational, IP, or commercial potential
- Late-stage clinical trials
- Development of tool compounds or biosimilars without mechanistic or translational novelty

Funding decisions will be made by the Colton Consortium Leadership in partnership with an External Advisory Board. All proposal materials and deliberations will be handled confidentially throughout review and assessment.

### **Applicant Eligibility**

This RFA is specifically designed to incentivize and expand collaboration across the four Colton Centers (Penn, Yale, NYU, TAU) within the Colton Consortium. Proposals are *strongly encouraged* include investigators from all 4 Colton Centers.

All Colton Consortium faculty (assistant, associate, and full professors, including research-track appointments) are eligible to submit proposals.

Early- and mid-career investigators are particularly encouraged to apply, and interdisciplinary applications are also strongly encouraged.

**TAU Colton center affiliated centers stuff** (E.G Sheba MC, TLVMC, Hadassah Medical Organization, Wolfson MC, Shaare Zedek MC, as well as Meuhedet Health Services and Clalit Health Services), are eligible to submit only with a **co-PI from the senior academic staff member employed by Tel Aviv University 100% in the research tenure track.**

### **Awards**

The Colton Consortium anticipates awarding a single project for a minimum of 1 year, providing approximately \$600,000 in direct costs. Future year funding may be considered based on success in Year 1.

Award announcements are expected by July 2026, with funding to commence immediately thereafter.



THE COLTON CONSORTIUM  
FOR AUTOIMMUNITY

## Submission Instructions and Guidelines

1. Each investigator may submit only one proposal per grant cycle.
2. The proposal should include:
  - Cover page
    - Name, Title, Department, Proposal Title, Type of Grant
    - 3-line non-confidential summary
  - Specific Aims
  - Background & Relevance to Monogenic Autoimmune or Immune-Dysregulatory Disease
  - Innovation
  - Research Strategy
  - Milestones (month 6 and 12)
  - Lay Summary of Project and Expected Findings (~100-150 words)
  - Plan for Translational and Intellectual Property Development
    - Expected translational outcomes
    - Possible therapeutic, diagnostic, biomarker, or platform outputs
    - Potential for commercial or licensing pathways
  - Disclosure of any required Background IP, materials, or data
3. Written proposal (not including cover page) should be limited to 4 pages and use single spacing, 11-point font, 0.5-inch margins.
4. Each investigator should attach a signature from their Department Chair approving their proposal (not included in page count).
5. Please limit Figures to one page, with 0.5-inch margins (not included in page limit)
6. Please limit References to one page, with above margins (not included in page limit)
7. On a separate single page (form provided below), please provide a budget, including allocation for salaries, supplies, and other necessary items, with budget justification. PI salaries are restricted to no more than 5% of total costs requested. Salaries for other personnel are permitted.
8. Append NIH biosketch (5-page max) of PI and other key personnel.
9. Prepare entire application as one (1) PDF document containing all sections and with the file name LeadPILastName\_ColtonConsortiumMonogenicPilot\_FY26.pdf
10. Applications are due no later than **11:59pm on Friday, May 15, 2026**.
11. Applications should be submitted directly to Leonardo Guercio, PhD, Director of Strategy and Business Development, Colton Consortium for Autoimmunity.

## Terms and Conditions

Grant Term: 1 year, with possible no-cost extension and/or competitive renewal based on progress.



**Grant Conditions:** Successful awardees must become members of the Colton Consortium. Membership in the Colton Consortium requires participation in Colton Center for Autoimmunity symposia, seminars, as well as all Colton Consortium retreats and activities.

**Time and Effort:** All personnel must commit time and effort appropriate to their roles on the project. Funding may only be used for research approved by the Colton Consortium and may not be used for any other purposes. Budget items may not include equipment, computers, or travel, with PI salary limited to 5% effort at NIH cap.

**Research Plan and Milestones:** Awards are contingent upon approval of the research plan and milestones. An interim progress report will evaluate milestone completion at 6 and 12 months. Continuation or renewal may be considered if justified by significant progress. Projects may be terminated if agreed-upon goals and milestones are not met. It may be possible to revise the research plan and/or budget upon request during the project period, subject to approval from the Colton Consortium Leadership.

**Research Compliance:** Colton Consortium grants are considered internal funding. The PI(s) and department(s) are responsible for meeting all compliance requirements with the award, including all regulatory approval (IRB, IACUC, etc.), if applicable.

**Overlapping Funding:** Awardees must inform the Colton Consortium Leadership if internal or external funding is obtained to support any of the specific aims of the proposal. Overlapping funds provided by the Consortium may be reallocated by the PI provided those activities are directly related to the funded project and approved in writing by the Consortium Leadership.

**Expenditure of Funds:** All funds are expected to be expended within the grant term of the current award. If a carry-over of funding is needed, the PI should submit a letter for review to Colton Consortium Leadership at least 30 days before the grant period ends to allow sufficient time to process the request. The carry-over request should include the current expiration date of the project, the requested termination date, and a brief justification for the request.

**Reporting Requirements:**

A final progress report, with expense report, is required within 30 days of funding completion. The progress report should be limited to two pages maximum and must include a 100-200 word lay summary of progress, specifically addressing the goals of the project, the key findings, and its broader public health impact.

**Inventions and Intellectual Property:** Applicants must disclose any relevant Background IP or existing agreements (e.g., MTAs, SRAs, licenses). Any new IP (“Project IP”) arising from the project will be managed jointly through the participating institutions’ technology transfer offices, in accordance with each institution’s IP policies.

**Publications:** All publications and presentations must acknowledge support from the Colton Consortium for Autoimmunity and be forwarded to Leonardo Guercio, PhD, Director of Strategy and Business Development, upon submission.

**Budget Form**

See attached PDF.