



# Request for Proposals:

## *Ann Theodore Foundation Breakthrough Sarcoidosis Initiative*

The Ann Theodore Foundation is launching a new scientific program focused on funding sarcoidosis research in partnership with the Milken Institute Center for Strategic Philanthropy.

The Milken Institute is now accepting applications for research projects up to two years in length that seek to understand the biology of sarcoidosis and increase our understanding of the genetic, molecular, and immunological aspects of the disease.

### Description:

The Ann Theodore Foundation Breakthrough Sarcoidosis Initiative (ATF-BSI) intends to award four to six two-year research grants led by doctorate-level investigators at qualifying research-based institutions in the US. Projects led by individual researchers will be eligible for up to US\$200,000 in funding for direct costs per year plus 15 percent in indirect costs, totaling \$230,000 per year. Interdisciplinary teams comprised of a sarcoidosis expert and a researcher from a separate field relevant to the project will be eligible for up to \$250,000 in funding for direct costs per year plus 15 percent in indirect costs, totaling \$287,500 per year. Funded investigators will be able to apply for a third year of funding.

Sarcoidosis is a disease that is hallmarked by clusters of immune cells, known as granulomas, forming in various organs throughout the body. Sarcoidosis usually affects the lungs, but virtually any organ can be impacted. In some cases, it resolves spontaneously, but for others it can be a chronic debilitating condition. The symptoms can include difficulty breathing, fatigue, and arrhythmia, and if the granulomas persist, they can cause severe organ damage and death. Approximately 1 in 2,000 people in the US is affected by sarcoidosis; however, it impacts African American women at higher rates than other demographics. While sarcoidosis is often considered a rare disease, its true prevalence may be higher due to underdiagnosis and a lack of awareness among clinicians. Environmental exposures and genetic risks have been implicated in the onset of sarcoidosis. Additionally, autoimmune and infectious causes of sarcoidosis have been studied, but more work is needed to understand the mechanism and etiology of the disease.

### A Need for Novel Approaches to Study Sarcoidosis:

Sarcoidosis is a multidimensional condition, and it will require attention and investment from individuals working in various fields to answer its most pressing questions. **We encourage not only those who work in sarcoidosis but also those who work on autoimmune diseases, infectious conditions, inflammatory conditions, and other fields to apply. Applicants without prior sarcoidosis research experience do not have to apply with a sarcoidosis expert to be eligible for funding.** Sarcoidosis requires study from a variety

of perspectives, including but not limited to: genetics, epidemiology, molecular biology, immunology, and cardiology. Where possible we encourage investigators to develop research approaches that allow assessment and understanding across more than one relevant discipline.

Projects investigating sarcoidosis that may be selected for funding should display novelty, creativity, and promise in seeking innovative approaches to understand the etiology and molecular basis of sarcoidosis.

## Scientific Focus

The scientific focus of sarcoidosis proposals shall address one or more of the following focus areas in human, mouse, or cell models, though studies utilizing human models will be prioritized:

- Studies that elucidate the heterogeneity of clinical course within sarcoidosis, utilizing approaches inclusive of molecular biology, epidemiology, and polygenetic studies
- Investigations into the immunobiology of sarcoidosis, such as immunotyping and immunodissections
- Studies that elucidate the mechanisms of downstream effects in sarcoidosis (e.g., fibrosis)
- Studies that involve the application of new tools or technologies that will improve the understanding of the basic biology of sarcoidosis
- Investigations into the environmental, autoimmune, and/or infectious risks for sarcoidosis
- Studies that seek to understand the biology of granuloma formation, propagation, and persistence in sarcoidosis
- Development or improvement of a digital, cell, or animal model for further investigation of sarcoidosis

## Eligibility Criteria

1. Each applicant organization must be a nonprofit academic or research institution, including domestic nonprofit organizations and domestic public/private academic universities or institutions of higher learning (including colleges, universities, medical schools, and other related academic research institutions); certain qualified governmental agencies with active biomedical research programs may also apply. Institutions not located in the United States are ineligible at this time.
2. All proposed research projects must be led by a Principal Investigator (PI) who holds a PhD, MD, or related research doctorate degree. The PI must be an independent investigator.
3. Institutions may submit more than one proposal, but each proposal must be led by a unique PI.

## Letter of Intent (LOI) and Application Requirements

All completed LOIs and applications shall be submitted through the Milken Institute's online grant portal, found at <https://Milken.smapply.io/prog/sarcoidosisgrant>.

It is recommended that each applicant keep in mind the portal's requirements when preparing the application. **Applications shall be single-spaced and formatted in Calibri 11 pt font with 1-inch margins, except where provided templates apply.**

All applicants are invited to submit an **optional LOI**, which shall be reviewed by the Milken Institute's review team. The LOI will be an opportunity for initial feedback on the project. Applicants who propose

relevant projects will be notified that their project falls within the scope of the program. If the Milken Institute informs an applicant that their project does not fall in the scope of the program, the applicant is still able to submit a full proposal, but the Milken Institute would advise changing the scope of the project. As the LOI is optional, all applicants are able to submit a full proposal, regardless of their submission of an LOI.

- 1. Optional letter of intent.** The LOI is a one-page letter briefly stating intent to apply for a grant, project title, and project aims. The LOI also requires the applicant organization's legal name; PI name, degree, position, and contact information; and the organization's tax ID (for US) or registered charity number.
  - a. LOIs are due Wednesday, November 10, 2021, at 11:50 p.m. Eastern Time.
  - b. LOIs should be submitted via the Milken Institute's online grant portal, which can be accessed via this link: <https://Milken.smapply.io/prog/sarcoidosisgrant>
  - c. Should the Milken Institute, in its sole discretion, find that a project described in an LOI falls in the scope of the program, the applicant will be notified by email within approximately two (2) weeks of the LOI submission deadline. The LOI is an opportunity for initial feedback and provides a chance to alter the project as needed before submitting a full proposal.
  
- 2. Proposal.** A formal proposal outlining the intended project shall be no more than eleven (11) pages in length, outlining the intended project, and will be organized as follows:
  - a. Cover page. One (1) page, including the following:
    - i. Project title (a short title identifying the project and its intended area of focus).
    - ii. Lay summary (succinct summary intended for a public audience describing the project's aims, goals, any previous accomplishments, and how it will benefit the field).
    - iii. Name of applicant institution and principal investigator.
  
  - b. Project summary page. One (1) page, including the following:
    - i. Technical abstract.
    - ii. Aims and milestones (summary of what the project aims to accomplish and the major milestones the PI anticipates the project will complete in the process of meeting project aims). Aims should include future plans for the project. Major milestones should include estimated time frame of completion.
    - iii. Full roster of project team members.
  
  - c. Scientific Approach (outline of which research methodology the PI intends to use in pursuit of the project, in addition to defining and justifying key project outcome measures). Four (4) pages maximum, inclusive of references in the applicants' preferred format.
    - i. All proposals must be focused on the biology, biochemistry, epidemiology, or immunobiology of sarcoidosis. Studies that are only tangentially related to sarcoidosis will not be considered.
    - ii. Proposals must be accompanied by a brief protocol synopsis and timeline milestones. As noted below, IRB (for human studies) or IACUC (for animal studies) approval will be required before initial payment is made for any project that the ATF-BSI, in its sole discretion, selects for funding. If new approvals are required

during the course of funding, those approvals should be submitted to the ATF-BSI as soon as possible.

- iii. Studies of human participants or utilizing patient samples should specify a recruitment or acquisition plan that will be inclusive of diverse backgrounds as much as possible, including race, gender, ethnicity, and geography, if possible.
  - iv. Any intellectual property considerations that the proposed research may entail should be noted.
  - v. Any clinical study of an interventional strategy should include a discussion of how participants will be selected, how efficacy will be assessed, participant diversity, necessary sample size, and control populations.
  - vi. If alternative plans exist that would be implemented should local conditions prevent research from proceeding as planned, please include a brief description of these arrangements.
- d. Team capabilities (statement outlining the research group's ability to address the research question, support the research, manage patients, if applicable, and identification of any key personnel in addition to the PI). One (1) page maximum.
- e. Data sharing plan (specifying the applicant organization's commitment to, and plan for, sharing project results and data (de-identified, where applicable)) with other institutions and researchers for non-commercial use to advance the understanding of sarcoidosis and to maximize scientific impact, including designation of the particular data repository to which the applicant intends to upload and share such project results and data, and policies and procedures for ensuring that the applicant organization's PI and all other applicable employees and contractors will comply with and adhere to such plan. One (1) page or less.
- f. Budget (a detailed budget in USD with a narrative summary and justification for each item, including how the PI intends to spend their time on the project). Two (2) pages in length using the provided template and one (1) page in length providing narrative justification of budget items. Projects can be budgeted for two years. Projects led by individual researchers can be budgeted for \$400,000 in direct costs and \$60,000 in indirect costs if they are two years in length, and projects led by interdisciplinary teams comprised of a sarcoidosis expert and a researcher from a separate field relevant to the project can be budgeted for \$500,000 in direct costs and \$75,000 in indirect costs if they are two years in length. Note: If more than one institution will be involved in the project, one shall be proposed as the applicant organization, and the other included as a sub-grantee. Acceptable expenditures for direct costs include:
- i. Salary for the PI, graduate students, postdocs, and staff scientists, and other personnel. Fringe benefits are also covered.
  - ii. Equipment and software
  - iii. Patient recruitment
  - iv. Project-related travel, including to the Funded Investigators Meetings, the first of which will be held in July 2022
  - v. Publication costs
  - vi. Up to an additional 15 percent indirect expenses to support institutional infrastructure. Indirect expenses will be proportional to either the \$400,000 direct

costs budget, and therefore will not exceed \$60,000, or the \$500,000 direct costs budget, and therefore will not exceed \$75,000. It is not necessary to provide specifics on the indirect cost expenditures.

3. Additional documentation within the online form will include:
  - a. Lead PI's biosketch from the NIH template. Five (5) pages or less using the NIH template.
  - b. Completed electronic signature confirming that the grant proposal contains information that is true, complete, and accurate and that false or fraudulent statements may subject the institution to criminal, civil, or administrative penalties.
  - c. Institutional letter of commitment stating that applicant institution will be able to support the research led by the PI.
  - d. Organizational assurances: Upon request, an applicant institution may be required to submit additional information to document its nonprofit status.
4. US-based governmental organizations (excluding academic/research institutions that are public charities) must provide:
  - a. A full copy of the enabling statute that authorized the organization's creation.
  - b. A copy of the organization's governing documents (such as articles of organization or constitution and bylaws), if applicable.
  - c. Any correspondence from the IRS confirming the organization's tax status, if applicable.

Formatting and length shall be strictly enforced by the review team. Any submissions that exceed the page limit or do not follow the aforementioned requirements shall not be considered for review.

## Review

Milken Institute will seek independent expert review for each application. All applications will be reviewed based on:

- their scientific and technical merit,
- team capabilities and competencies,
- the potential impact of the project on the field of sarcoidosis, and
- the realism of the cost.

Milken Institute does not offer feedback on proposals for projects that are not selected for funding.

## Key Dates and Timeline

1. **Wednesday, November 10, 2021:** Optional letters of intent due via Milken Institute's online grant portal by 11:59 p.m. Eastern Time.
2. **Friday, November 19, 2021:** Those who submitted an LOI will be notified whether their proposed project is within the scope of the program. Those who submit an LOI are permitted to make modifications to the project before submitting a full proposal.
3. **Monday, January 10, 2022:** Applicants shall submit their full proposals via Milken Institute's online grant portal by 11:59 p.m. Eastern Time.

4. **March 2022:** Awardees who are selected for funding are notified.
5. **May 2022:** Projects begin.
6. **July 2022:** The Inaugural Funded Investigators Meeting takes place.

## Grant Terms

Each funded research institution and the lead investigator will be required to co-sign and agree in writing to the ATF-BSI's grant terms within thirty (30) days from receipt of notice of the award and prior to funds being released. The ATF-BSI's grant terms include the following:

1. Signature confirming that the information provided in the grant proposal is true, complete, and accurate. False or fraudulent statements may subject the funded organization to criminal, civil, or administrative penalties.
2. Any substantial changes to the project including activities, budget, or grant period require written approval from the ATF-BSI before proceeding with such activities, spending or committing any remaining funds from the grant.
  - a. Any funds not expended or committed for the purposes of the grant must be returned to the ATF-BSI unless otherwise agreed by the Foundation in writing.
  - b. If an applicant organization proposes to supplement any funds provided by the ATF-BSI with funds provided by a third party, the organization must first provide notice to the ATF-BSI and must ensure that the funding terms that attach to any such third-party funds do not preclude sharing of data or publication of project results as contemplated in this RFP.
3. The applicant organization must be able to receive awarded funds and allocate them toward the funded sarcoidosis research project.
4. The funded investigators must submit a lay, non-confidential scientific abstract intended for a public audience for the ATF-BSI to display on their website.
5. The funded investigators are expected to attend and participate in annual investigators meetings to present and discuss their research plan and preliminary results in the research supported by the ATF-BSI. The first annual investigators meeting is planned for summer 2022.
6. Funded organizations must agree to the following reporting requirements:
  - a. Submission of full written narrative and financial reports at the conclusion of the granting period, at twenty-four (24) months, following the award payment.
  - b. At twelve (12) and eighteen (18) months after receiving funding, applicants shall also share brief updates describing major project highlights and/or progress based on pre-determined milestones after the initial award payment as well as participate in a brief virtual meeting with other grant recipients to discuss plans, progress, and findings.
7. IRB (for human studies) or IACUC (for animal studies) approval will be required before initial payments are made.
8. At 18 months, funded investigators may be eligible for an additional year of follow-on funding based on satisfactory completion of milestones and program alignment at the sole discretion of ATF-BSI.
9. It is a condition of any funding provided by the ATF-BSI that the investigator seek to have the results of the funded project submitted to a peer-reviewed, open access journal or a pre-print journal within

eighteen (18) months after the completion of the project. Each publication would acknowledge the ATF-BSI's role in supporting the project, in a form approved by the ATF-BSI. If the investigator does not publish the results within such timeframe, the ATF-BSI would have the right to make such results public. It is acceptable to publish in journals that give an option to make a publication open access after a period of time, though we encourage investigators to have the publication open access as early as possible. Specific financial support for such publications will be provided.

## Data and Intellectual Property

Each funded organization would own the rights in all intellectual property developed on behalf of that organization under ATF-BSI funding, in accordance with such organization's applicable intellectual property policies. The ATF-BSI would have the right to use and to practice all such intellectual property for internal, non-commercial research purposes, and would also have the right to publicly disclose research results in press releases, announcements, and otherwise (subject to the funded organization's advance approval if any such public disclosure will occur prior to publication of the applicable results).

Each funded organization must agree to share projects results, data (de-identified where applicable), reagents, and other research tools developed under ATF-BSI funding with other ATF-BSI funded investigators for non-commercial use to advance the understanding of sarcoidosis and to maximize scientific impact.

## Funding Awarded in ATF-BSI's Discretion:

Responding to this RFP, submitting an LOI, and/or submitting a full proposal does not entitle any individual or institution to receive funding from the ATF-BSI. Funding, if any, would be provided in ATF-BSI's sole discretion pursuant to the terms of a written grant agreement executed by the ATF-BSI and the selected awardee institution and acknowledged by the PI.

## Contact Information

For all inquiries about the online process, necessary documentation, research priorities, or scientific requirements, please contact [sarcoidosisgrant@milkeninstitute.org](mailto:sarcoidosisgrant@milkeninstitute.org).

An automated email confirmation is generated upon submission of the application. If you do not receive a confirmation within 24 hours of submitting your application, please check spam filters and then contact [sarcoidosisgrant@milkeninstitute.org](mailto:sarcoidosisgrant@milkeninstitute.org).

