

TAU Colton Center for Autoimmunity Tel Aviv University

January 2024

RFP: Research Proposals for the Study of Autoimmune Diseases

The **Colton Center for Autoimmune Disease Research at Tel Aviv University (TAU)**, together with partnering medical institutions, is inviting proposals for research in the field of autoimmune diseases. The purpose of the Center is to support broad-scoped studies that are likely to significantly improve the understanding, prevention, diagnosis, and treatment of autoimmune diseases.

The Center will support all types of research, while placing an emphasis on research that will use medical big data and methods from the data sciences. For this purpose, the Colton Center has forged strategic partnerships with the Sheba Medical Center and the Tel-Aviv Sourasky Medical Center, as well as Meuhedet Health Services and Clalit Health Services (and the hospitals affiliated with it). The Center plans partnerships with additional medical institutes. These partners will enable extensive use of medical records, at no cost, for the use of existing information.

Deadline for submitting proposals 7/4/2024 (20:00, Israel)

1. Focus for proposals

The proposed studies may deal with any aspect of autoimmune diseases, including:

- Studying a specific mechanism relevant to a particular disease or group of diseases.
- Multidimensional study of a particular disease (e.g., genomics, lifestyle, exposure to different disease-provoking factors, etc.)
- Examining the connections between autoimmune diseases and other diseases (comorbidity).
- Development of new methods that are significant for the study of autoimmune diseases or for the diagnosis of autoimmune diseases (e.g., new imaging methods or monitoring tools, development of new assays, development of new tests, etc.)
- Development of new treatment methods or repurposing of existing medications.
- Any other subject bearing potential importance for understanding, prevention, diagnosis, or treatment of autoimmune diseases.

2. Grant funds and duration

The proposed studies are expected to lead to a deep change in the understanding, diagnosis or treatment of autoimmune diseases. To achieve this goal, the selected proposals will receive significant resources. Studies that prove to be successful may receive funding in three consecutive installments.

The first grant award will be **up to \$200,000**, contingent on the nature of the research and on reaching significant milestones during the research period. While this grant is intended

for a period of two years, research projects may use the budget in a shorter period of time, as well as request an extension for the use of the funds.

Proposals may request a significantly lower budget, while committing to limited deliverables, providing it is clear how the success of such a preliminary study can potentially lead to a significant breakthrough, in this study or in a successive one.



From the end of the first year of the research, after the initial results have been obtained, the researcher or research group can apply for continued funding contingent on meeting the milestones. This additional funding can reach \$400,000 for a similar or longer period. The proposal will be re-evaluated, with added considerations given to the research record of the team and its ability to meet the milestones as agreed.

Accomplishing the research goals in the second period will allow the submission of a third grant request identical in size. Thus, the total grant award can reach \$1,000,000, in three installments.

The proposals will be evaluated semiannually during the research period to track the project's progress and milestones. The research committee reserves the right to approve an extension of the research period or to discontinue funding of research at any point in time in accordance with meeting milestones, and the scientific or applied significance of the results achieved.

It should be noted that reporting negative results does not necessarily imply the termination of a study, nor prevent its renewal. If the research team's performance shows its continuous effort to yield results, applying new research directions based on the lessons of the results obtained, then continuance of the study may be granted, as well as additional funding.

3. Research methods

The Colton Center is prepared to support all types of studies, including "wet" lab research, psychological research, engineering studies, theoretical studies, and clinical studies.

In addition, a main purpose of the Colton Center is to increase the use of existing medical data in studies of autoimmune diseases. The studies will combine the analysis of medical data available from the Center's partner institutions. The data may include all the medical information existing in the partner institutions, i.e., records of medical history, samples of physiological and/or genomic data, radiology scans, etc. The data may be used in any of the following ways:

- Defining the research goal (for example, examine relations between variables, forecast
- Identifying changes in a disease stage due to exposure to risk factors, forecasting treatment results, or unravelling the course of the disease).
- As means to assist in identifying new research directions that will be advanced in the framework of the proposal.
- As means to validate results achieved in preliminary experimental or theoretical research.

All research methods, directions for research and data sources are relevant, with a preference for the use of medical information.

4. Composition of research groups and assisting personnel

Research proposals can be submitted by individual researchers or research groups. Nevertheless, due to the complex character of the diseases, it is anticipated that even single lab studies will develop into studies involving researchers from different disciplines.

Eligibility to submit proposals – researchers, faculty and personnel at Tel Aviv University, and at the medical centers affiliated with TAU, at Meuhedet Health Services, or at Clalit Health Services (in the community or in its hospitals) are eligible to submit proposals. There are no conditions on the academic or medical rank of those submitting a proposal, but at least one principal investigator (PI) must be a senior academic staff member employed by Tel Aviv University 100% in the research tenure track. This PI will head the group and by

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virtue of this role, will be responsible for representing the group to the Colton Center, and the research authority. In either case, there is no limitation on the inclusion of researchers from Israel or from abroad as partners or as external advisors that are not funded. It is also possible to hire services from external clinical institutes or companies. There are no conditions on the academic or medical rank of those submitting a proposal, as long among the principal investigators (PI) in the research group, **at least one PI senior academic staff member employed by Tel Aviv University.** A PI can be a partner in **only one** research proposal.

- Support in setting up the research group establishment of a complete research team including all the researchers needed from different disciplines, prior to submitting the proposal, is not a condition for being awarded a grant. The Colton Center staff can assist those submitting proposals to connect with researchers in other fields to form a research group. The support for the establishment of the group can be given prior to or in the early stages of submission, or after the research grant is awarded.
- Collaboration with data scientists a priority will be given to studies that will make use of medical big data, so it is anticipated that the research group will also include data scientists. The Colton Center can assist in connecting with these researchers.
 An open list of scientists, in a range of fields that may be relevant to the Center's research will be available in the following <u>link</u>. Researchers interested in appearing on the list should send a short bio, and their contact details to <u>coltontauaic@tauex.tau.ac.il</u>
- Collaboration with scientists from non-partner institutions –research groups may include researchers from Israel and elsewhere in the world as partners or consultants, but they are not eligible to receive funding. Paid services may be received from hospitals, research groups, or external companies. The Colton Center is open to expanding the partnership with additional institutions. If there is interest in full funding of researchers and students who are not affiliated with the mentioned institutions, or in partnerships that involve aspects of intellectual property, please contact the Colton Center to discuss the matter.
- **Appointment of an industry advisor** upon request, the Colton Center will appoint an advisor who is experienced in project management. The advisor will assist the team in identifying research directions, bottlenecks or failures in project and risk management. The advisor's activity will be paid by the Colton Center, outside of the budget approved for the awarded project.
- **Supporting personnel** The Colton Center will provide personnel aiding to set infrastructure that will serve multiple studies. This includes administration, building an infrastructure to work with databases, managing ethical permits, supporting multi-site studies, if needed, and supporting other needs that may arise.

5. Format of the proposal – use the following <u>template</u>.

6. The review process and the review criteria

The proposals submitted will be reviewed by the Center's steering committee, who will be aided by a scientific advisory committee. The two committees are composed of senior researchers and physicians from the partner institutions and from external institutions. Members of the two committees are prohibited from being funded. Applicants of the best proposals will be called to appear in person, in front of a committee to present and discuss their proposal. Below is a list



of the criteria for the selection of the winning proposals (the proposal does not necessarily have to meet all criteria):

- The innovativeness of the proposal.
- Clear and focused research hypothesis, research question, and research methodology.
- Research with the potential for scientific breakthroughs and significant impact on the lives of patients of autoimmune diseases.
- Multidisciplinary research making use of medical records and including researchers and methods from the fields of statistics, data science and artificial intelligence. Moreover, special weight will be given to proposals that involve researchers from scientific fields that may seem unusual or even 'surprising', as long as this increases the synergy in the group and serves the purpose of the research.
- Potential for collaboration with other Colton Centers (see clause 7).
- A detailed and applicable research plan.
 - A gradual research plan that will reduce the chance of losing time and money on erroneous research directions Setting major and achievable milestones during the research period, with an emphasis on milestones both in the mid-term of the study and at its conclusion. The recommendation is to set significant milestones to be met at various stages of the research, but refrain from overly ambitious milestones, that would impede research progress presented at evaluation points.
 - A proportionate budget that minimizes the risk of losing substantial resources in the case of failure.
 - Strategies and alternative plans to cope with potential flaws in the research hypothesis.
- Research that leverages existing capabilities in Israel, such as an incidence level that enables significant clinical research or the existence of a collaborative community with an interest in the respective disease in Israel.
- A research approach that focuses not only on the immune system, but also on the damaged tissue or tissues related to the disease (for example: microbiome, brain and mental state, etc.).
- The existence of a unique research opportunity such as a new research hypothesis, preliminary results, or novel research methods.
- Research proposals that include significant funding of the proposed research by other funding sources.

7. Collaboration with the network of Colton Centers

The Research Center at Tel Aviv University operates together with three Centers established in the United States – at New York University, Yale, and the University of Pennsylvania. The Center encourages studies that can leverage the potential for collaboration among research teams at the different Centers. **Collaborative studies with these institutes may request additional funding and will be favored in the review process** The list of studies funded by the three universities is available for use by applicants <u>in this link</u>.

A study may propose a collaboration with the other groups at these universities or that will make use of the existing research infrastructure at these universities.



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8. Research operation

- **Initiation** discussions between the research authorities of the different institutions are expected to begin immediately following the award announcement, to initiate the research as quickly as possible, preferably before summer 2024.
- Use of funds funding can be used for any purpose that will serve the approved research, including perishable materials, equipment, animals and cells for experiments, computers, other peripheral or engineering equipment, software
- licensing, cloud services, analyses of tests and samples, salaries, stipends, services, scientific publications, etc.
- Financial supplements and limitations-
 - Medical data is obtained as part of the collaboration between the different partner institutions that agreed to participate in the research operation at the Colton Center. There will be no charge for using medical information that was anyway sampled (or that will be sampled) as part of a medical treatment.
 - There will be no charge for support from personnel of the Colton Center who assist in administration, IT management, planning of multi-site sampling experiments, commercial guidance, or other infrastructural assistance.
 - Capital equipment costing more than \$20,000 may not be purchased with grant money. Researchers requiring such equipment for their research can submit a separate request. The decision regarding such an acquisition will take into account the equipment's value as part of the infrastructure of the Colton Center, relative to alternatives if there are any. The acquisition will be funded separately from the research grant, and the equipment will be available in TAU for the activity of all active research groups.
 - Funds will not be used to support travel or hosting. The Center will accept separate requests for these needs, if they are directly research related. In such cases funding will be external to the grant budget.
 - Funds may not be used for salary support of any of the PIs.

Management of the research budget will be done by the Research Authority of Tel Aviv University. Accordingly, the rules for ethical use of funds for various needs will be in accordance with the rules in effect at Tel Aviv University.

- Sharing infrastructure and medical information funded studies will be entitled to use research infrastructure at Tel Aviv University and in the participating medical institutions. At the same time, each research group with its medical faculty members will be able to make use of historical medical information, as well as collect new information, with assistance from the medical partner with which the researchers are affiliated.
- **Periodical evaluation** grant recipients will briefly present their progress to the Center's management once every six months. Progress entails not only research outputs, but also the development of methods, tools and datasets. Towards the end of the first year of the grant, grant recipients are required to submit a progress report with details on milestones achieved and budget use, compared to the submitted plan. The report will be reviewed by the Colton Center staff and discussed with the research leader, prior to approval of the budget for the second year. If needed, and in accordance with the milestones' timeline; a request can be made to expedite or postpone the submission of the annual report.



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9. Publication of the research proposals awarded grants

- The winning research proposals will be published on the Colton Center website, including the names of the participating researchers, the title of the study, and an abstract of the proposal submitted.
- Grant recipients must acknowledge the Colton Center for Autoimmune Disease Research at Tel Aviv University in any publication, conference, or report detailing achievements made with support of the center.
- Grant recipients are required to present their research at an annual conference of the Center in Israel, as well as at the conference of all four Colton Centers that will be held in the United States.

The proposal must be submitted in the form of this template, along with a one page CV for each PI.

The submission should be on **one PDF file** containing all the submission materials to the following email: <u>coltontauaic@tauex.tau.ac.il</u>.

For enquiries, please contact: galilerman@tauex.tau.ac.il

Please visit our website: https://en-colton.tau.ac.il