OSTEOSARCOMA INSTITUTE

concentrating on the cure®

2024-2025 Grant Cycle Application Instructions

Letter of Intent Due: October 31, 2024 (by 4:00 p.m. Eastern Time)
Full Proposal Due: April 1, 2025 (by 4:00 p.m. Eastern Time)

Submit via Proposal Central:
https://proposalcentral.com
Recommended Browsers: Google Chrome or Mozilla Firefox

For additional questions or information, please email:
submissions@osinst.org

Published by the Osteosarcoma Institute on August 30, 2024

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THE OSTEOSARCOMA INSTITUTE OVERVIEW

MISSION

To dramatically increase treatment options and survival rates in osteosarcoma patients through identifying and funding the most promising and breakthrough osteosarcoma clinical trials and science.

HISTORY

The Osteosarcoma Institute (OSI) was established in 2017 with the goal of improving the outcomes of patients with osteosarcoma. It was envisioned by the What Would Willie Want (QuadW) Foundation, which was created in 2005 to honor the memory of Willie Tichenor, who lost his life to osteosarcoma at age 19. QuadW convened a conference in 2015 to challenge experts in osteosarcoma research to expedite work that could improve outcomes. This meeting led to the formation of the OSI, with a foundational grant from QuadW.

GRANT STRATEGY

The OSI is a science-driven organization whose strategy is guided by its active and engaged Strategic Advisory Board of preeminent physicians and other researchers from academia and industry. In pursuit of its mission, the OSI employs a multi-faceted strategy in which grant funding plays an important role. Our grant programs provide both immediate hope to patients through clinical trials and long-term hope through earlier-stage translation of scientific ideas that have the potential to result in a new treatment. Our correlative science grants are designed to answer critical questions that are too often ignored during clinical trials due to lack of funds: Is the drug under study having the biological effect in patients that it was hypothesized to have based on preclinical data? If not, why not? With this information, even a failed clinical trial can point the way to an advance. Our fourth category, High Risk/High Impact grants, exists to enable the study of novel, untested but intriguing ideas that would otherwise be rejected by the customary, risk-averse criteria of grant proposal evaluation. The objective of all our preclinical grants is to identify and advance scientific ideas toward the clinic.

Today, the OSI has committed $6.5 million toward a comprehensive portfolio of 14 funded studies. We maintain a high level of involvement and accountability with our grantees through regular and rigorous progress reporting.

GRANT PROGRAM DESCRIPTIONS

CLINICAL TRIALS

SCOPE OF PROPOSAL

The primary objective of proposed Phase I/II or Phase II clinical trials in relapsed/refractory osteosarcoma should be to improve event free survival (EFS) at 4 months beyond historical rates known to be in the range of 12% for patients with unresectable disease. The proposed trial may be carried out in a single institution, a clinical trial consortium, or through an existing clinical trial infrastructure. OSI will not prioritize the launch of new infrastructures to conduct clinical trials. Please provide specific timetables for protocol development, regulatory approvals, industry agreements, IRB approvals, activation, accrual, and reporting. We will consider the applicant's history of efficiently entering agreements, opening trials, and meeting accrual expectations for trials of relapsed osteosarcoma patients, with the expectation that results will be available within three years of trial initiation. Other desirable characteristics for proposals include:

- Answering an important question
- Strong preclinical rationale
- Rigorous trial design and correlative endpoints to allow for productive failure.
- Budget reasonableness (per patient and total)
- Leverage from concurrent financial support of the trial (e.g., direct institutional support, industry and/or philanthropic support, securing drug, etc.)

BUDGET

Up to $800,000 total over two to three years (inclusive of indirect costs not to exceed 10% of the requested project budget).

CORRELATIVE SCIENCE

SCOPE OF PROPOSAL

Correlative studies should seek to generate data from clinical trials aimed at improving event free survival of recurrent and metastatic osteosarcoma patients. Our highest priorities for correlative science proposals are to create the opportunity, should the associated clinical trial fail, to understand the reasons for that failure and allow for productive iteration of the approach; and 2) to identify specific predictors of response. Nonetheless, proposals may include hypothesis testing and/or exploratory, hypothesis generating elements, but all proposals should include/prioritize the following:

- The generation of new biology data associated with a clinical trial that will improve our understanding of osteosarcoma metastasis and/or accelerate the launch of future clinical or translational osteosarcoma studies.
- Power analyses demonstrating the number of samples from patients needed to answer each correlative question proposed to be answered, and the rationale for asserting that the required samples will be obtained.
- Preliminary data demonstrating technical ability to apply desired technology for biological analysis to relevant osteosarcoma biospecimens.

BUDGET

From $200,000 – $500,000 total over two years (inclusive of indirect costs not to exceed 10% of the requested project budget).

PRECLINICAL/TRANSLATIONAL

SCOPE OF PROPOSAL

A translational imperative for the OSI is to cultivate and support a research agenda that will identify biological dependencies in the disease that can be targeted in patients. This research agenda will ideally include the use of novel laboratory approaches and bioinformatic tools applied to osteosarcoma cells, a diversity of in vivo models across species and human patient samples. Furthermore, we are particularly interested in the study of dependencies that may impact a variety of potential phenotypes associated with the disease, including metastatic proclivity, DDR in the context of a structurally complex genome, identifying novel disease targets using surfaceome approaches, targeting mechanisms of resistance to first generation T cell checkpoint blockade in osteosarcoma, and other immunotherapeutic opportunities. While we value projects designed to enable new clinical studies, we also realize and value foundational research studies that will identify the desired biological dependencies/targets.

BUDGET

Up to $500,000 total for two years (inclusive of indirect costs not to exceed 10% of the requested project budget).

HIGH-RISK/HIGH-IMPACT

SCOPE OF PROPOSAL

Grantmaking involves balancing the potential impact of a successful research project with the risk of experimental failure. Traditionally, risk mitigation is accomplished during the research proposal review process in several ways, including heavily weighing preliminary data. While the historical balance point has proven broadly effective and successful, the stubborn lack of progress in osteosarcoma suggests that alternatives should be considered. Thus, the aim of this grant program is to place less emphasis on preliminary data in order to encourage projects exploring bold innovations that may fall within any stage of the drug development path, and that seek to deliver curative outcomes to patients with osteosarcoma. Proposals will be most valued based on their innovation and sound scientific hypothesis, and the likelihood that the approach will address a true dependency in osteosarcoma.

The desired criteria for this high-risk/high-impact osteosarcoma drug development research are:

- Bold ideas that will generate evidence of success or failure within 12 months.
- A new research direction rather than a continuation of ongoing funded research.
- While preliminary data are not required, the applicant must demonstrate feasibility of a persuasive research plan.
- Rigorous, quarterly interactive grant progress reviews to be used to guide ongoing direction and distribution of research support.

A successful high-risk/high-impact grant proposal should have one or more of the following characteristics:

- A proposal that, upon successful conclusion of the project, may mature into a successful submission for a traditional OSI grant or launch a translational development plan with investigators, institutions, or commercial biopharma companies.
- An existing relationship that makes the development of a therapeutic asset in biopharma feasible.

BUDGET

From $25,000 – $125,000 total over one year (inclusive of indirect costs not to exceed 10% of the requested project budget).

GENERAL INSTRUCTIONS FOR ALL GRANT PROGRAMS

GRANT PROCESS OVERVIEW

The OSI utilizes a two-stage grant process. In early fall of each year, we issue a call for Letter of Intent (LOI) proposals. In the New Year, we convene expert review committees to evaluate the LOIs and select finalists who progress to the second stage and are invited to submit full proposals during the spring. The full proposals are evaluated, and grants are awarded in July.

We do not limit our work by geography or primary institutions. Instead, we invite the brightest minds in the field to apply for funding for research studies and revolutionary trials of unexplored aspects of osteosarcoma. In recognition of the effort to submit an LOI and full proposal, and with the objective of improving future applications, every applicant receives detailed feedback about their submission from our reviewers following the LOI and full proposal stages. We have seen that this work has resulted in higher quality submission.

APPLICATION DEADLINES AND REVIEW TIMELINES

Letter of Intent Deadline	October 31, 2024 (by 4:00 p.m. Eastern Time)
Letter of Intent Decision	February 2025
Full Grant Submission Deadline	April 1, 2025 (by 4:00 p.m. Eastern Time)
Funding Decisions Sent to Applicants	July 2025

Note: The following application procedures and timeline constitute the primary OSI grantmaking cycle, which is the preferred method of applying for a grant. OSI recognizes that not all projects are compatible with these time restrictions; accordingly, we consider out-of-cycle proposals on a case-by-case basis. Additionally, the OSI has a Discretionary Grant Program for new and innovative ideas that need a relatively small, but timely investment to establish feasibility for further development in osteosarcoma. Please visit the OSI website here for more information on off-cycle and discretionary grant programs.

ELIGIBILITY CRITERIA (MUST BE MET AT THE TIME OF SUBMISSION)

- Funds must be granted to nonprofit/charitable institutions or organizations.
- Grantee organization does not need to be based in the United States.
    - However, in order to fund a foreign entity, the OSI requires documentation that if the entity were a United States-based organization, the entity would qualify as a charitable organization. This is usually relatively straightforward when dealing with entities in countries with a tax regime similar to the U.S. by way of a government-issued letter or other document designating the entity as a charitable institution or as performing a charitable purpose (for example, research or education). It might also be a determination from the relevant taxing authority that the entity qualifies for tax-deductible contributions.
- Applicants need not be United States citizens.
- Applicants must have an MD, PhD, MD/PhD, or equivalent and be appointed as faculty (or equivalent) at an academic institution.
- Applicants must have a track record of publication and funding productivity that demonstrates the project can be accomplished by the investigators.
- Applicant must propose a new research direction, not a continuation of ongoing funded research.
    - All established researchers requesting funds should show how their project is a departure from ongoing funded work. New projects may be an extension of other work but cannot overlap any funded studies unless the applicant clearly demonstrates that new funding will not duplicate existing support.
- Applicants selected for funding will permit the OSI to publicize the grant for fundraising purposes, including, but not limited to a five-minute video discussing the research project, photos of lab, and photos of children participating in clinical trials, where applicable.
- Applications that do not follow the specific grant application instructions and/or submission process will not be considered.
- Applications received after the due date will not be considered.
- Applications which do not fall under the OSI mission will not be considered.
- **Resubmissions:** Only one resubmission of a previously reviewed application is permitted.

GRANT INSTRUCTIONS FOR ALL PROGRAMS (CONTINUED)

INDIRECT COSTS

Indirect costs cannot exceed 10% of the total OSI requested funding AND budgets may not exceed the amounts stated above in the grant program descriptions **inclusive of indirect costs**. In other words, no more than 10% of the OSI's funds can go to indirect costs. Also, we do not use the Modified Total Direct Cost base.

APPLICATION SUBMISSION INSTRUCTIONS

First time users must register as a new user in ProposalCentral to begin the application process. The recommended browsers for accessing the application are Google Chrome and Mozilla Firefox. Only applicants who submit an LOI and are approved may submit a full proposal. The PI will be notified via email if the LOI is approved or rejected. If approved, the PI will then have access to the full proposal in ProposalCentral. The PI who submits the LOI should be the same PI that submits the full proposal.

To locate the OSI Grant Programs, select the "Grant Opportunities" tab and enter "Osteosarcoma Institute" in the search box. The application form is available by clicking "Apply Now" on the appropriate line for the following grant programs:

- Clinical Trials Grant Program
- Correlative Science Grant Program
- Preclinical/Translational Grant Program
- High-Risk/High-Impact Grant Program

Note: Access can be granted to other users by using the "Enable other users to access this proposal" link.

FORMATTING INSTRUCTIONS FOR ATTACHMENTS

- Calibri or Times New Roman Font (minimum 11-point font for text and no smaller than 9-point font for figures, legends, and tables).
- Single-spaced text is acceptable, and space between paragraphs is recommended.
- In the Project Description, pages must be numbered consecutively.
- 0.75-inch minimum margin.
- Only PDF files are accepted.

CONTACTS

- ProposalCentral Customer Support: pcsupport@altum.com / Phone: 800.875.2562
- The Osteosarcoma Institute: submissions@osinst.org

SUMMARY OF GRANT AGREEMENT TERMS

Agreement with the following is required to receive an OSI grant. Please ensure that you and your institution can accept these terms. This section is for informational purposes only – the grant will be governed by a formal written agreement negotiated between the grantee and OSI which will be the controlling, authoritative document.

GENERAL

Customary organizational assurances from the lead institution regarding such matters as, as applicable, adherence to GLP, compliance with the Animal Welfare Act and applicable chapters of the Public Health Service Policy on Humane Care and Use of Laboratory Animals, subcontracting including the requirement that subcontractors comply with the terms of the grant agreement, and other matters as are typically covered in a research grant agreement.

We desire that the project work start as quickly as possible and are intent on an expeditious path to execution of the grant agreement with no unresolved contingencies. In negotiating the grant agreement, your institution must commit to assign persons with sufficient authority to avoid multi-level, multi-step approvals and meet the contract execution timelines. Any subcontracts must be fully executed before grant funding and must be reviewed and approved by the OSI.

FUNDING SCHEDULE

Grant funding typically includes an initial, start-up payment for a portion of the full grant amount. The initial payment will be due only after grantee, in consultation with the PI, advises OSI that work on the project is ready to begin. Subsequent scheduled grant payments are subject to the receipt by the OSI of scheduled 6-month and 12-month deliverables demonstrating satisfactory progress toward the completion of the proposed research aims/objectives and expenditures consistent with the budget. Grants are not renewable; one no-cost extension may be requested. Please request the extension in the End of Project Final Report and detail the work to be completed during the extension and budget detail for the extension.

REPORTING

The Principal Investigator must provide a research Progress Report (detailing progress on each specific aim) including a lay summary updated each year for the public and a financial report (expenditures compared to budget) at the end of each 6-month reporting period. Subsequent year(s) of funding (if applicable) will be contingent on timely submission of completed deliverables and the OSI Executive Committee's review and approval. For multiple year grants, Progress Reports (for the first 12-month reporting period) will be due 14 months after the start date of the award. In addition, annual and end-of-project, in-person or, at OSI's option, videoconference review of grant progress with members of the OSI's scientific staff is required. The OSI will reimburse reasonable travel and associated out-of-pocket costs incurred by the PI in connection with any in-person progress reviews. The Sponsoring Institution will be required to submit an End of Project Final Report, including a full financial accounting of funds spent, within sixty (60) days after the end of the award period.

Periodic update reports, including but not limited to email requests, phone calls, and video interviews, may be requested on occasion to support the OSI in efforts to raise funds, attract major donors, and meet other operational needs.

Customary confidentiality provisions will apply.

PUBLICATION AND PUBLICITY

Subject to reasonable and customary intellectual property considerations, PI will agree to publicize the results of the project at scientific conferences and use reasonable best efforts to have results published in a scientific journal. The OSI support of the project will be cited. The Principal Investigator will promptly advise the OSI of all such activity. Grantee will permit the OSI to publicize the grant, including a synopsis of the project, identifying the PI and institution, and allowing the use, solely for this purpose, of grantee or its appropriate division's logo. The OSI will abide by grantee's guidelines for such use.

GRANT PROGRAM-SPECIFIC APPLICATION INSTRUCTIONS

CLINICAL TRIALS GRANT PROGRAM

LETTER OF INTENT (LOI) INSTRUCTIONS

The LOI Project Description can be no more than 10 pages. **It is REQUIRED that you include all of the sections below in this specific order for your LOI to be considered (pages must be numbered consecutively):**

1. Trial rationale and expected impact of a successful outcome
2. Hypothesis
3. Objectives (primary, secondary, and exploratory)
4. Endpoints (primary and secondary)
5. Key inclusion/exclusion criteria
6. Summary treatment plan with trial schema
7. Statistical Plan: expected sample size, sample size justification, analysis plan, interim monitoring for futility
8. Data handling and monitoring patient safety
9. Trial sites and labs
10. Description of correlative studies
11. Timeline from grant award to reporting of results: please provide specific timetables for protocol development, regulatory approvals, industry agreements, IRB approvals, activation, accrual, time on study, analysis, and reporting.
12. Budget summary by project year (inclusive of indirect costs not to exceed 10% of the requested project budget)
13. Summary of other anticipated support (Institutional/Philanthropic/Industry/Other)
14. References Cited

In addition to the above, applicants are required to complete the following sections in ProposalCentral:

- Title Page
- Download Templates & Instructions
- Enable Other Users to Access this Proposal
- Applicant/PI
- Institution & Institutional Contacts
- Attachments
  - Biosketch – Applicant/PI (5-page maximum)
  - Project Description (to include all sections listed above in order; 10-page maximum)
- Sign/Print Application
- Validate
- Submit

CLINICAL TRIALS GRANT PROGRAM (CONTINUED)

FULL PROPOSAL INSTRUCTIONS

Please be sure to address the comments provided to you by the OSI from your LOI submission. Additionally, certain fields on the application in ProposalCentral are pre-populated from your LOI submission. You may leave these as-is, add to, or otherwise modify them.

The Project Description Template can be found on ProposalCentral. **It is REQUIRED that you include all of the sections in the specific order for your full proposal to be considered (pages must be numbered consecutively).** If a section is not relevant, still include the section title and denote it as not applicable.

Applicants are also required to complete the following sections in ProposalCentral:

1. Title Page
2. Download Templates & Instructions
3. Enable Other Users to Access this Proposal
4. Applicant/PI
5. Institution & Institutional Contacts
6. Letters of Support
7. Key Personnel
8. Collaborators
9. IRB/IND Approval
10. Intellectual Property
11. Patient Advocacy
12. Budget Period Detail
13. Budget Summary
14. Other Support for Research
15. Proposal Attachments
    - Biosketches (2 to 5 biosketches allowed per application; 5-page maximum per biosketch)
    - Budget Justification (2-page limit per institution)
    - Clinical Trial Project Description
    - Clinical Trial Project Timeline
    - Letters of Support (minimum of 2 and maximum of 5 letters are allowed)*
    - Protocol/White Paper
16. Sign/Print Application
17. Validate
18. Submit

***Additional guidance regarding Letters of Support:** Two (2) Letters of Support are required. If there is only one institution involved and no other collaborators or companies, you could have two different people from your institution's leadership submit a Letter of Support. As far as who should write the letters, that is at the PI's discretion and can be an individual in a leadership position at the institution. For instance, we often see applications with Letters of Support from the PI's department head and/or a dean, assistant dean, director, etc.

CORRELATIVE SCIENCE • PRECLINICAL/TRANSLATIONAL • HIGH-RISK/HIGH-IMPACT

LETTER OF INTENT (LOI) INSTRUCTIONS

The LOI Project Description can be no more than 5 pages. **It is REQUIRED that you include all of the sections below in this specific order for your LOI to be considered (pages must be numbered consecutively):**

1. Project rationale and expected impact of a successful outcome
2. Hypothesis
3. Specific aims
4. Statistical plan
5. Research strategy (including protocol/s)
6. Summary budget by project year (inclusive of indirect costs not to exceed 10% of the requested project budget)
7. Summary of other anticipated support (Institutional/Philanthropic/Industry/Other)
8. References Cited

In addition to the above, applicants are required to complete the following sections in ProposalCentral:

- Title Page
- Download Templates & Instructions
- Enable Other Users to Access this Proposal
- Applicant/PI
- Institution & Institutional Contacts
- Attachments
  - Biosketch – Applicant/PI (5-page maximum)
  - Project Description (to include all sections listed above in order; 5-page maximum)
- Sign/Print Application
- Validate
- Submit

CORRELATIVE SCIENCE • PRECLINICAL/TRANSLATIONAL • HIGH-RISK/HIGH-IMPACT (CONTINUED)

FULL PROPOSAL INSTRUCTIONS

Please be sure to address the comments provided to you by the OSI from your LOI submission. Additionally, certain fields on the application are pre-populated from your LOI submission. You may leave these as-is, add to, or otherwise modify them.

The Project Description Template can be found on ProposalCentral. **It is REQUIRED that you include all of the sections in specific order for your full proposal to be considered (pages must be numbered consecutively).**

Applicants are also required to complete the following sections in ProposalCentral:

1. Title Page
2. Download Templates & Instructions
3. Enable Other Users to Access this Proposal
4. Applicant/PI
5. Institution & Institutional Contacts
6. Letters of Support
7. Key Personnel
8. Lay Project Summary
9. Budget Period Detail
10. Budget Summary
11. Other Financial Support
12. Proposal Attachments
    - Biosketches (2 to 5 biosketches allowed per application; 5-page maximum per biosketch)
    - Budget Justification (2-page limit per institution)
    - Letters of Support (minimum of 2 and maximum of 5 letters are allowed)*
    - Project Description (Proposal)
    - References Cited (1-page limit)
13. Sign/Print Application
14. Validate
15. Submit

***Additional guidance regarding Letters of Support:** Two (2) Letters of Support are required. If there is only one institution involved and no other collaborators or companies, you could have two different people from your institution's leadership submit a Letter of Support. As far as who should write the letters, that is at the PI's discretion and can be an individual in a leadership position at the institution. For instance, we often see applications with Letters of Support from the PI's department head and/or a dean, assistant dean, director, etc.

ADDITIONAL RESOURCES

2024-2024 GRANT CYCLE
https://osinst.org/researchers/#grants

NEWSLETTER SIGN UP
https://osinst.org/patients/#sign-up
Sign up as "doctor/researcher" to receive information on our annual grant cycle.

RESEARCHER RESOURCES
https://osinst.org/researchers/

***THE FRONTLINE* BLOG**
https://osinst.org/blog/