

ROI 2022–23 Request for Proposals

A New Era of Radiotherapy

Deadline for Letters of Intent (required for all applicants): November 10, 2022 Deadline for Project Proposals (by invitation only): March 3, 2023

Purpose and Background

Advances in technology are transforming the practice of radiation oncology. New radiotherapy techniques have the potential to increase personalization in cancer care, but much more research is needed to understand how they can be used safely and effectively to improve outcomes for patients. Threats such as cybersecurity that now can disrupt our ability to reliably treat patients will require novel, technical solutions. In support of this new era of radiotherapy, ROI is requesting proposals for research on new methods including but not limited to:

- FLASH radiotherapy
- Spatially fractionated radiation therapy (SFRT) including GRID and LATTICE
- Particle therapy
- Novel treatment delivery techniques such as personalized ultrafractionated stereotactic adaptive radiotherapy (PULSAR)
- Immuno-radiotherapy
- Technology to address disruptions in radiation care such as cybersecurity threats

By supporting innovative investigators exploring the frontiers of radiotherapy, ROI will drive the field forward and help shape the future of radiation oncology.

Intent

Through this RFP, ROI is seeking to advance research on new radiotherapy methods that have the potential to transform practice and improve outcomes for patients. ROI focuses on research to heighten the critical role of radiation therapy in the treatment of cancer and identified the following topics through the *National Radiation Oncology Research Needs Assessment** to form its research agenda.

- **Quality and safety** establishing general quality indicators for radiation oncology treatment.
- Comparative effectiveness conducting comparative effectiveness outcomes studies.
- **Toxicity management** identifying best practices for management of radiation toxicity and survivorship.
- **Value** assessing the value of radiotherapy/radiation oncology relative to other treatment modalities.
- **Communication** identifying and developing communication strategies to improve awareness and understanding of radiotherapy by referring physicians, patients and others.

The proposed research on new radiotherapy methods must also address one or more of ROI's priority topic areas. Proposals should focus on the highest impact research questions for the field of radiation oncology. Projects resulting in tangible deliverables with practical applications for radiation oncology professionals and their patients such as, decision support tools, educational materials, additional grants, abstracts, and manuscripts

will be given priority. Knowledge derived from these studies should aim to improve patient outcomes in cancer treatment or the survivorship experience. Special consideration will be given to proposals that use highly innovative methodologies or are not otherwise fundable through traditional sources.

*An executive summary of the *National Radiation Oncology Research Needs Assessment* is available at <u>www.roinstitute.org</u>, or see the following publication: *Int J Radiat Oncol Biol Phys.* 2012;84(2):318-322.

Award Amount

A typical budget for a project supported by this mechanism is expected to be limited to a total of \$50,000 over 2 years. However, larger budgets will be considered with the firm limit that costs may not exceed \$100,000. Special attention will be given to projects that demonstrate efficiency and economy of resources to pursue the research proposed. ROI will not pay indirect costs, but applicants should contact ROI at <u>roi@astro.org</u> if they could experience a hardship due to this policy.

The number of grants in each funding cycle is not predetermined by ROI. Awards are made based on application merit and the availability of funds.

Grants may be approved for up to a two-year period. Funding for the second half of the grant period is contingent upon submission and approval of an interim progress report. Projects must start by August 1, 2023 and end no later than **July 2025**.

Eligibility

- 1. Qualified individuals from institutions and organizations in the radiation oncology (RO) community.
- 2. Applicants enrolled in residency programs or post-doctoral fellowships require a faculty mentor.
- 3. Individuals from institutions and organizations of the non-RO community who possess necessary qualifications for specified research.
- 4. Applications from research consortia.
- 5. The Sponsoring Institution that will receive and manage the grant funds must be a qualified 501(c)(3) organization or government-sponsored university in the United States or their equivalent in Canada.*

*Applicants not affiliated with a 501(c)(3) organization or government-sponsored university are eligible but should contact <u>roi@astro.org</u> for more information about identifying a Sponsoring Institution prior to submitting an LOI.

General Selection Criteria

Proposals for research projects will be judged by ROI on several criteria based on scientific and technical merit. An application does not need to be equally strong in all categories to be judged likely to have major scientific impact.

- 1. **Overall Impact:** Likelihood for the project to lead to significant follow-on funding or initiate a new research direction that will eventually have a powerful influence on the field of radiation oncology.
- 2. <u>Significance/Importance</u>: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field? The application MUST address clearly what the expected end-product is, the value of the end-product to the radiation oncology community, and how the product will be used for follow-on funding or to initiate a new research direction that will benefit the broader radiation oncology community.
- 3. <u>Topic and Practical Application</u>: How well does the project address one or more of ROI's priority research areas identified in the *National Radiation Oncology Research Needs Assessment*? Will the project advance new radiotherapy methods and result in tangible deliverables? Are the outcomes from the project designed to have an impact on practice in the near future? Are the outcomes scalable?

4. <u>Approach</u>: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of at-risk groups (e.g. children), justified in terms of the scientific goals and research strategy proposed?

Applicants proposing observational studies are specifically referred to the following methods overview published in the *International Journal of Radiation Oncology Biology and Physics*:

Jagsi R, Bekelman JE, Chen A, Chen RC, Hoffman K, Tina Shih YC, Smith BD, Yu JB. Considerations for observational research using large data sets in radiation oncology. *Int J Radiat Oncol Biol Phys.* 2014;90(1):11-24.

- 5. <u>Innovation</u>: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- 6. <u>Investigator</u>: Are the PD/PIs, collaborators, and other researchers well suited to the project? If early-stage or new investigators, do they have appropriate experience, training, and mentorship? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; is their leadership approach, governance and organizational structure appropriate for the project?
- 7. <u>Research Environment</u>: Would the scientific environment in which the work would be done contribute to the probability of success? Would there likely be institutional support for this project? Would the project benefit from unique features of the scientific environment, or subject populations, or require useful collaborative arrangements?
- 8. **<u>Budget:</u>** Does the budget reflect appropriate use of resources to complete the project in a timeline consistent with what has been outlined in the proposal?

How to Apply

1. Letter of Intent – Required for All Applicants

Submit a Letter of Intent (LOI) by **November 10, 2022, at 5:00 p.m. ET** through ProposalCentral. ROI will review the LOIs and will send notifications in December about proceeding to the next step in the process of preparing and submitting a project proposal. The LOI consists of the items listed below and a separate letter is not required. Each applicant may submit only one LOI for this RFP.

Application and Signatures

Complete all of the required fields in the application form on ProposalCentral (project title, estimated budget, applicant's name, institution, contact information, other key personnel, etc.). ROI strongly encourages PIs to set up an ORCiD profile and link it to their application. Electronic signatures must be submitted through ProposalCentral. **The e-signatures of the applicant and an authorized institutional official are required on all LOIs.** Residents and fellows applying for an award must list a Faculty Mentor under Other Key Personnel, and the Faculty Mentor's e-signature is also required.

Abstract

Enter a preliminary technical abstract. The abstract should include the significance and innovation of the proposed research, the study question, the specific aims to be accomplished and a brief description of the experimental approach for each aim in a maximum of 4,000 characters including spaces. A system-generated page will be included in the application and a separate document does not need to be uploaded.

Statement of Relevance

Write a statement about the relevance of the proposed research to one or more of the ROI's priority research topics (communication, safety and quality, toxicity management, comparative effectiveness and value) and how the research will impact practice and benefit patients. The statement of relevance should be no more than 2,000 characters including spaces. A system-generated page will be included in the application and a separate document does not need to be uploaded.

Principal Investigator Biosketch

Upload the Principal Investigator's biosketch with selected relevant publications (following NIH format and not to exceed 5 pages) in the "Attachments" section of the LOI. The Faculty Mentor's biosketch must also be submitted if the PI is a resident or fellow.

2. <u>Project Proposal – By Invitation Only</u>

After receiving an invitation to proceed, submit a proposal by **March 3, 2023, at 5:00 p.m. ET** through ProposalCentral. Proposals must contain the items below.

Application and Signatures

Complete all of the required fields in the application form on ProposalCentral (project title, applicant's name, institution, contact information, other key personnel, etc.). ROI strongly encourages PIs to set up an ORCiD profile and link it to their application. Electronic signatures must be submitted through ProposalCentral. **The e-signatures of the applicant and an authorized institutional official are required.** Residents and fellows applying for an award must list a Faculty Mentor under Other Key Personnel, and the Faculty Mentor's e-signature is also required.

Abstracts

Enter both a technical abstract and a lay abstract. The technical abstract will carryover from the approved LOI, and minor edits can be made prior to submitting the final proposal. The lay abstract should be a clear and concise summary for the general public and media. The technical abstract can be a maximum of 4,000 characters including spaces, and the lay abstract should be no more than 2,000 characters including spaces. System-generated pages with these items will be included in the application and a separate document does not need to be uploaded.

Statement of Relevance

The statement of relevance will also carryover from the approved LOI. Small modifications are allowed to clarify how the proposed research applies to one or more of the ROI's priority research topics (communication, safety and quality, toxicity management, comparative effectiveness and value) and how the research will impact practice and benefit patients. A system-generated page will be included in the application and a separate document does not need to be uploaded.

Proposal

Upload a brief project description (up to 4 pages, single-spaced, including figures) that contains:

- A statement of the project's principal objectives
- A discussion of significance, outcomes and impact, including the value of the end-product to the radiation oncology community
- A statement of innovation
- A description of the research plan and methodologies to be employed, including clear discussion of how data will be collected
- A plan for evaluation that will measure the outcomes of the project in terms of the purpose and objectives
- A description of the tangible deliverables including, decision support tools, educational materials, abstracts and manuscripts, and additional grants resulting from the project
- A clear discussion of next steps and dissemination strategy
- A timetable

Budget

Grant funds may be used to support project staff salaries and benefits, consultant fees, data management, supplies and other direct expenses. All costs must be entered into the Budget Detail section and a justification describing each line item must be included in the Budget Summary & Justification section of the application on ProposalCentral. Be sure to include details on the following items:

- Personnel List the names and roles of all professional and non-professional personnel involved in the project and whether or not salaries and benefits are requested. Costs for the salary and benefits of the Principal Investigator may be requested but are limited to 20% of the total award amount or a maximum of \$10,000, whichever is lower. Costs for the salary and benefits of residents and clinical fellows are not permitted. Indicate the percent effort on the project for all personnel. The institutional base salary of an individual should not exceed the current federal salary cap established by NIH at the time of the proposal submission.
- Consultant fees Give the name and institutional affiliation of any consultant and a brief description of the services to be performed.
- Equipment and Supplies Equipment purchases are allowed with sufficient justification. List all items requested and the cost of each item.
- Travel Describe the purpose of any travel. Meeting travel expenses can only be charged if presenting an abstract that includes results of the ROI-funded research.
- Other Direct Expenses Itemize other expenses by major categories, such as publication costs, data management, etc.

In the justification, an explanation of how costs to carry out the research not covered by this grant, such as departmental funds or other grants, will be paid is also required. Any other grant sources of funding supporting the same scope of work must be reported to the ROI if not described in the original proposal.

References Cited

References should be numbered in the sequence that they appear in the text (not to exceed 1 page).

Biographical Sketches

Upload biosketches with selected relevant publications for all of the key project personnel (following NIH format and not to exceed 5 pages each). This includes Co-PIs for all projects and/or the Faculty Mentor's biosketch if the applicant is a resident or fellow.

Letters of Support

A letter of support from the department chair or other institutional research leader is required. Additional letters from collaborators or faculty mentors are optional.

Appendices

Only include if necessary to communicate essential information, but please limit to 2 pages (e.g., excerpts from in-press papers, essential figures or other media).

Transition Plan – Required for Residents and Fellows

Residents and fellows must upload a statement that outlines a plan for the completion of the project if their training concludes and they move to another institution before the project has ended.

Proposal Formatting

- Font Use an *Arial, Helvetica, Palatino Linotype, Calibri or Georgia* typeface, a black font color, and a font size of 11 points or larger.
- Page Margins Use at least 0.5 inch margins (top, bottom, left, and right) for all pages.
- Page Formatting Single-spacing should be used, and applicants are strongly encouraged to use only standard, single-column format for the text. Page numbers should be included.
- Proposals are not to exceed the 4-page maximum (excludes application form, abstracts and statement of relevance, budget, references, biosketches, letters of support, appendices, and transition plan).

Submission

Applications should be submitted electronically at: <u>https://proposalcentral.com</u>. After logging-in, click on the "Grant Opportunities" tab and select "Radiation Oncology Institute" in the "Filter List by GrantMaker" dropdown menu. Customer support with online submissions will be provided by ProposalCentral by email at <u>pcsupport@altum.com</u>, or phone at 800-875-2562 (toll free U.S. and Canada) or 703-964-5840 (direct dial international). Customer support specialists are available Monday through Friday from 8:30 a.m. to 5:00 p.m. ET. For questions regarding the ROI research program, please contact ROI by email at <u>roi@astro.org</u> or by phone at 703-839-7356.

Evaluation of Proposals

All proposals are evaluated by the ROI's Research Committee, whose recommendations are reviewed by the ROI Board of Trustees. Funding of awards is based on the priority score awarded to each application and the recommendations of the Research Committee. Relevance of the proposed study to the ROI's research agenda is also considered in determining awards.

1. Scoring Proposals:

- Each LOI and proposal will be scored by at least two qualified reviewers.
- No individual who submits an application in response to this RFP or is designated as key personnel, including the mentor of an applicant, may score applications for this RFP.
- Applications from the same institution or organization will not be scored by members of the ROI Research Committee, subcommittee or work group from that institution or organization.

2. <u>Timeline:</u>

Letter of Intent due	November 10, 2022 at 5:00 p.m. ET
Invitation for proposal submission	-
Proposal due	
Award notification	

Other Requirements

All grant recipients must submit an interim report to ROI after one year and a final report at the end of the twoyear funding period. This timeline will be adjusted as needed if the grant period is less than two years. Investigators are expected to submit an abstract to present their results at an ASTRO meeting. Manuscripts should be submitted to peer-reviewed journals with a large U.S. audience. Investigators must acknowledge ROI support on all publications and products of the project and send copies of all publications and products to ROI.

ROI will review all submissions and make a determination as to whether to release the funds to the selected participant as 1) a grant pursuant to standard terms related to grants and ownership of all work product related thereto or 2) to offer the funds through a program services agreement. An applicant whose project has been selected will be notified of ROI's choice under the above two scenarios and upon agreement enter into either of the appropriate relationships with ROI.