



*Improving Cancer Care
Through Research and Education*

2015 Request for Proposal

Examination of the Comparative Value of Radiation Therapy

ROI Mission:

The Radiation Oncology Institute (ROI) will enhance and promote the critical role of radiation therapy in the treatment of cancer by supporting research and education about the life-saving and quality-of-life benefits of radiation therapy.

Deadline for Letter of Intent: January 23, 2015

Deadline for Project Proposals: April 24, 2015

Purpose and Background:

The aim of this request is to stimulate research to examine the comparative value of radiotherapy. The ROI, ASTRO, NCI and IOM call for generation of evidence to demonstrate the value of technologies and interventions in radiation oncology. Value encompasses aspects of both comparative and cost effectiveness but can be more broadly defined to include innovative approaches to evaluating the benefits and harms of radiation oncology interventions. The ROI supports studies that examine the comparative value of radiotherapy because such studies have the potential to generate the evidence needed to improve cancer outcomes while slowing the growth of health care spending.

This Call for Proposals is intended to:

This call for proposals aims to examine the comparative value of radiotherapy. The ROI seeks proposals that address the highest impact research questions for the field of radiation oncology. Knowledge derived from these studies will inform policy development and enhance outcomes in cancer treatment. Special consideration will be given to studies which examine 1) how patient, provider, facility, hospital, and healthcare system structural factors impact the access, use, quality, outcomes, or costs of radiation therapy as compared to non-radiotherapy interventions; 2) how the structure and capacity of cancer delivery impact access, use, quality, outcomes, and costs of radiation therapy as compared to non-radiotherapy interventions; and 3) how insurance plan benefit designs, ACOs, medical homes, and other insurance instruments impact access, use, quality, outcomes, and costs of radiation therapy as compared to non-radiotherapy interventions.

We encourage submission of studies proposals that leverage any design or dataset that is responsive to this call for proposals; of particular interest is research using the most up to date registry or administrative databases, including CMS datasets, Medicare or commercial claims and payment datasets, state datasets, or other existing datasets. Focus on one or several of the prevalent cancers is encouraged. To examine the comparative value of radiation therapy, several broad topic areas are also proposed below; however, the ROI seeks any proposal that would lead to important research that addresses value in radiation oncology.

Example 1: Locoregional control and function preservation are defining goals of radiation therapy. Studies might examine how one or more of the factors described above affect access to or outcomes and costs of functional preservation strategies.

Example 2: Productivity outcomes are important to characterize the impact of cancer in the workplace and show the effects of treatment on productivity. The analysis of lost productivity is complementary to conventional cost-effectiveness studies. The cost of lost productivity may be considerably greater than direct medical costs and may be minimized by advances in radiation therapy technique and delivery. Studies might examine productivity loss for patients and their caregivers associated with alternative approaches to definitive cancer care (radiotherapy versus surgical, systemic or other approaches) using retrospective administrative datasets.

Example 3: Definitive Radiotherapy: Studies might evaluate the comparative and/or cost effectiveness of definitive radiation therapy modalities compared to surgical or other definitive approaches. Studies comparing radiotherapy to non-radiotherapy treatments are of particular interest (e.g., stereotactic body radiotherapy versus surgery).

Example 4: Adjuvant Radiotherapy: Studies might evaluate the comparative and/or cost effectiveness or comparative productivity gains associated with adjuvant radiotherapy compared to other adjuvant approaches (chemotherapy or biologics). Comparisons of the value of adjuvant radiotherapy in disease sites where Level I evidence supports its use (i.e., prevalent cancers like breast, lung, prostate, and gastrointestinal cancers, etc.) to the value of adjuvant systemic therapies are of particular interest.

Award Amount:

Total costs for this project may not exceed \$200,000; a maximum of up to 7% can be attributed to indirect costs from this amount. Special attention will be given to projects that show efficiency and economy of resources to arrive at a plausible conclusion. The project cannot span more than two years, though it is anticipated that many applications will require no more than 1 year to complete the research.

Projects must be completed no later than **July 2017**.

Eligibility

1. Qualified individuals from institutions and organizations in the radiation oncology (RO) community.
2. Applicants should have completed their post-doctoral training and should not be enrolled in residency or fellowship programs, although supervised participation of trainees in the conduct of the project is permitted (and encouraged)
3. Vendors with required expertise to conduct specified ROI research.
4. Individuals from institutions and organizations of the non-RO community who possess necessary qualifications for specified research.
5. Applications from research consortia (the same maximum overhead rate will apply to both the primary award and all subcontracts).

General Selection Criteria

Proposals for research projects reviewed by ROI will be judged 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 exert a sustained, powerful influence on the field of radiation oncology.
2. **Significance/Importance.** 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 preventative interventions that drive this field?

The application MUST address clearly what the expected end-product is and how the product will be useful to the broader radiation oncology community.

3. **Approach.** 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 is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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

Considerations for Observational Research Using Large Data Sets in Radiation Oncology.

Jagsi R, Bekelman JE, Chen A, Chen RC, Hoffman K, Tina Shih YC, Smith BD, Yu JB.

Int J Radiat Oncol Biol Phys. 2014 Sep 1;90(1):11-24.

4. **Innovation.** 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?
5. **Investigator.** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? 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; are their leadership approach, governance and organizational structure appropriate for the project?
6. **Research Environment.** 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?
7. **Overall Research Plan:** Does the proposal demonstrate understanding of the project's goals? Does the proposal identify appropriate research questions to be answered? Does the proposal describe a sound technical approach, including description of any process elements? Is the project design and methodology feasible?
8. **Budget:** 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:** Submit a letter of intent to submit a proposal by January 23, 2015. The letter of Intent should include a [working] title and a preliminary project abstract (not to exceed 250 words) as well as a biosketch of the principal investigator. ROI will review the Letters of Intent and send notifications to proceed to the next step in the process of preparing and submitting a project proposal. Submit your letter of intent using the following site: <https://proposalcentral.altum.com>

2. **Project Proposal:** Interested researchers must submit proposals that contain the following items:

- A project abstract (not to exceed 250 words).
- A lay summary paragraph written to be understandable to the public/patients and media, explaining the project and the contribution it will make to the field of radiation oncology and the care of cancer patients
- A project description (up to five pages, single-spaced) which contains the following information
 - o A synopsis of the proposed project
 - o A statement of the project's principal objectives, significance and impact, and innovation
 - o A description of the research plan and methodologies to be employed
 - o A clear discussion of how data will be collected
 - o A clear discussion of next steps
 - o A dissemination strategy
 - o A timetable
- Project budget justifying specific items requested and assigning a priority to each item (not to exceed one page)
- Applicant's biosketch with selected relevant publications (following NIH format but not to exceed two pages)
- Amount of PI's current and past research support, and list of any other pending proposals for the same project
- Co-Investigator(s) biosketch(es) and any support pages with relevant publications (not to exceed two pages).
- Appendices (please submit these if necessary to communicate essential information but please limit to two pages; e.g., excerpts from in-press papers, essential figures or other media).

3. **Other Requirements :**

All investigators receiving funds must submit a final report to the ROI at the end of the funding period. Investigators may also be requested to present their results at research meetings at ASTRO or ROI. Investigators must acknowledge ROI support on all publications and products of the project and send copies of all products to ROI.

ROI will review all submissions and make a determination as to whether to release the funds to the selected participant as a grant pursuant to standard terms related to grants and ownership of all work product related thereto or to offer the funds through a services contract which would provide the ROI with ownership and/or a broad license to the work product created through the services and contract. A participant 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.

4. **Use of Grant Funds:**

Funds may be used to support project staff salaries and benefits, consultant fees, data management, supplies and other direct expenses. Equipment purchases are allowed with sufficient justification. A maximum of 7% of the total budget (\$13,084) can be used for indirect expenses.

5. **Proposal Formatting:**

- Font: Use an *Arial, Helvetica, Palantino 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 9 page maximum (excludes cover page, current and past research support documents, and appendices)

Evaluation of Proposals

1. Scoring Proposals:

- No individual who is designated as the mentor of or submits an application in response to this RFP 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
- An independent scoring body will be assembled to evaluate and score research proposals, which may consist of non-radiation oncology experts.

2. Feedback

- Each proposal will be scored by at least 5 qualified reviewers
- Individuals submitting an application will receive a score for that application

3. Timeline:

Letter of intent due.....January 23, 2015
Invitation for proposal submission.....February 13, 2015
Project proposal due.....April 24, 2015
Award announcement.....July 2015

Submission

Applications should be submitted electronically to: <https://proposalcentral.altum.com>. Customer support with online submissions will be provided by Proposal Central by email at pcsupport@altum.com, or phone at (800) 875-2562 (toll free) or (703) 964-5840. Customer support specialists are available Monday through Friday from 8:30 AM to 5:00 PM EST. For questions regarding the ROI Award program, please contact Liz Freedman, Research Program Specialist, by email: liz.freedman@astro.org or phone: 703-839-7356.