ROI 2018–19 Request for Proposals

Personalized Radiation Therapy

Deadline for Letters of Intent: December 14, 2018
Deadline for Project Proposals: March 1, 2019

Purpose and Background

Personalized medicine holds tremendous promise in the delivery of cancer care. Personalizing radiation therapy to each cancer patient’s unique characteristics has the potential to transform radiotherapy practice and improve outcomes. By tailoring an individual’s cancer care to their individual tumor characteristics and personal genetic profile, they can receive more targeted and effective treatments while minimizing side effects. This approach uses biomarkers, gene expression profiles, and other predictive tools to evaluate risks and guide treatment decisions designed to help patients live longer, healthier lives.

Although much of the emphasis on personalized medicine has been focused on drug development, radiation therapy is also moving away from the “one-size-fits-all” approach to treating cancer. Recent advances in our understanding of individual patient and tumor recurrence risks have improved the quality of treatment. As more is learned about the great variety in the genetics and biology of cancer, treatments, including radiation therapy, can be better tailored to individual patients, including whether their cancer will respond to radiation and their risk for toxicity and side effects. However, much more research is required to realize the potential of personalized radiation therapy.

Intent

Through this RFP, the ROI is seeking innovative ideas to advance the personalization of radiation therapy within its priority research areas. The ROI is focused on generating evidence to demonstrate the life-saving and quality-of-life benefits of radiation therapy and identified the following topics through the National Radiation Oncology Research Needs Assessment to form its research agenda.

- **Communication** – identifying and developing communication strategies to improve awareness and understanding of radiotherapy by referring physicians, patients and others.
- **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.

The proposed research can address 1 or more of the ROI’s priority topic areas. Proposals should focus on the highest impact research questions for the field of radiation oncology. Knowledge derived from these studies
should inform policy development or aim to improve patient outcomes in cancer treatment. Given the length of the study period, 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 would be received favorably. Focus on 1 or several of the prevalent cancers is encouraged, however, the ROI seeks any proposal that would lead to important research that aims to personalize radiation therapy. Projects resulting in practical applications for radiation oncology professionals and their patients will be given priority. Special consideration will be given to proposals that are not otherwise fundable through traditional sources.

Examples of projects that would be responsive to this RFP are included below.

Example 1: Use of patient gene profile or patient co-morbidity characteristics to assist treatment decision support to identify optimal primary disease management (i.e., primary radiation vs. surgery vs. multi-modal management).

Example 2: Using patient-specific demographic, disease, or dosimetric parameters to predict which cases may require greater vigilance during treatment and follow-up to promote quality and safety in care delivery.

Example 3: Utilize radionomics to predict response to radiation treatments including tumor response and short/long-term toxicities.

Example 4: Development of a decision support tool to help patients make radiation treatment choices based on their personalized preferences about treatment options that consider outcomes, toxicities, and cost.


**Award Amount**

Up to $300,000 in grants will be awarded, and multiple projects will be selected for funding. 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 $150,000. A maximum of 7% of the requested amount can be attributed to indirect costs. Special attention will be given to projects that demonstrate efficiency and economy of resources to pursue the research proposed.

Grants may be approved for up to a 2-year period. Funding for year 2 is contingent upon submission and approval of an interim progress report. Projects must be completed no later than **July 2021**.

**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 (the same maximum overhead rate will apply to both the primary award and all subcontracts).
5. Applicants from international and for-profit institutions will be required to submit additional documentation if invited to submit a full proposal.

**General Selection Criteria**

Proposals for research projects will be judged by the 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. **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 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 initiate a new research direction that will benefit the broader radiation oncology community.

3. **Topic and Practical Application**: How well does the project address 1 or more of the ROI’s priority research areas identified in the *National Radiation Oncology Research Needs Assessment*? Will the project advance the personalization of radiation therapy? Are the outcomes from the project designed to have an impact on practice in the near future? Are the outcomes scalable?

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


5. **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 1 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. **Investigator**: Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators 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. **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?

8. **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?
9. **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 (LOI) by **December 14, 2018 at 5:00 p.m. EST** through proposalCENTRAL. ROI will review the LOIs and will send notifications in early January 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.

   **Cover/Signature Page**
   The Signature Page is automatically populated with data entered in the proposalCENTRAL system (title of project, applicant’s name, institution, contact information, etc.). Download the Signature Page after completing the application by clicking on the “Print Signature Page” button in the “Signature Page” section of the LOI. For the LOI, the Signature Page must be signed by the **Principal Investigator**. If the applicant is a resident or fellow, the **Faculty Mentor** must also sign this page. Upload the signed Signature Page in the “Attachments” section of the LOI on proposalCENTRAL before submitting the entire application by the deadline. A hardcopy is not required.

   **Abstract and Statement of Relevance**
   Enter a preliminary technical abstract and a statement about the relevance of the proposed research to 1 or more of the ROI’s priority research topics and how the research will impact practice and benefit patients. The abstract should include a description of the study question and research plan in a maximum of 500 words (up to 4,000 characters max, including spaces). The statement of relevance should be no more than 250 words (up to 2,000 characters max, including spaces). A system-generated page with these 2 items 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 should also be included if the applicant is a resident or fellow.

2. **Project Proposal**: After receiving an invitation to proceed, submit a proposal by **March 1, 2019 at 5:00 p.m. EST** through proposalCENTRAL. Proposals should contain the items below.

   **Cover/Signature Page**
   The Signature Page is automatically populated with data entered in the proposalCENTRAL system (title of project, applicant’s name, institution, contact information, etc.). Download the Signature Page after completing the application by clicking on the “Print Signature Page” button in the “Administrative & Signature Page(s)” section of the proposal. For the proposal, the Signature Page must be signed by the **Principal Investigator and Authorized Institutional Official**. Upload the signed Signature Page in the “Project Proposal Supporting Documents” section of the proposal on proposalCENTRAL before submitting the entire application by the deadline. A hardcopy is not required.

   **Abstracts and Statement of Relevance**
   Enter both a technical abstract and a lay abstract as well as a statement about the relevance of the proposed research to 1 or more of the ROI’s priority research topics and how the research will impact practice and benefit patients. The technical abstract should be written for a scientific audience, while the lay abstract should be a clear and concise summary for the general public and media. The abstracts and statement of relevance should be no more than 250 words (up to 2,000 characters max, including spaces) each. A system-generated page with these 3 items 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) which contains the following information:

- A statement of the project’s principal objectives
- A discussion of significance 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 clear discussion of next steps and dissemination strategy
- A timetable

Budget
Include a project budget justifying specific items requested and assigning a priority to each item (not to exceed 1 page). Be sure to include details on each of the following items:

- Personnel - List the names and positions of all professional and non-professional personnel involved in the project, and whether or not salaries and benefits are requested. Indicate the percent effort on the project for professional personnel. The institutional base salary of an individual should not exceed the current federal salary cap of U.S. $189,600.
- 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.
- Other Direct Expenses – Itemize other expenses by major categories, such as publication costs, data management, etc.
- Indirect Expenses – A maximum of 7% of the total budget can be used for indirect expenses.

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.

Reference Letter
A maximum of 1 letter of reference can be submitted but is not required.

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).

3. Other Requirements: All investigators receiving funds must submit to the ROI an interim report after 1 year and a final report at the end of the 2-year funding period. Investigators are expected to submit an abstract to present their results at an ASTRO meeting. Manuscripts should be submitted to 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 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 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 2 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 can be used for indirect expenses.

5. **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 Signature Page, abstracts and statement
     of relevance, budget, references and biosketches).

**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:**
   - No individual who is designated as the mentor of an applicant or who 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.

2. **Feedback:**
   - Each LOI and proposal will be scored by at least 2 qualified reviewers.
   - Individuals submitting a full proposal will receive a score and a summary of feedback when
     available.

3. **Timeline:**

   **Letter of Intent due**.................................................................December 14, 2018 at 5:00 p.m. EST
   **Invitation for proposal submission**......................................................... January 2019
   **Proposal due**.............................................................................March 1, 2019 at 5:00 p.m. EST
   **Award announcement**...................................................................April 2019

**Submission**

Applications should be submitted electronically at: [https://proposalcentral.altum.com](https://proposalcentral.altum.com). After logging-in, click on the "Grant Opportunities" tab and select "Radiation Oncology Institute" in the "Filter List by GrantMaker" drop-down menu. Customer support with online submissions will be provided by proposalCENTRAL 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 p.m. EST. For questions regarding the ROI award program, please contact Emily Connelly, Governance and Research Administrator, by email at emily.connelly@astro.org or by phone at 703-839-7356.