



## **2022 Patient-Centered Clinical Research Young Investigator Award \$50,000 for one year**

### **Purpose of Award**

The IOM (Institute of Medicine) defines patient-centered care as: “Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.” This Award is intended to support the development of outstanding research scientists and clinical cancer research investigators who have demonstrated a commitment to improving the understanding, treatment, and experience of bladder cancer. Investigators must be working in a research environment capable of supporting transformational patient-oriented clinical bladder cancer research (e.g. studies of shared decision making, access to care, quality of care, quality of life, health disparities, comparative effectiveness research, patient-centered outcomes research, and survivorship – sample optional research questions available in Appendix A).

Applications will be evaluated on the quality of the applicant’s research plan and the resources and environment available to the applicant. This includes the ability of the primary mentor and relevant department to provide appropriate guidance and ensure sufficient protected time during the Award period to complete the research activities. It is the policy of BCAN not to provide indirect costs to the grant recipient’s institution.

### **Eligibility**

I. At the time of submission, the applicant must be within six years of completion of a professional degree such as MD, DO, PhD, MD-PhD, MPH, MS, DNP, DScPAS or equivalent, or clinical training such as residency or fellowship. The applicant may hold the title of Senior Postdoctoral Fellow, Instructor, Research Associate, Assistant Professor or equivalent. At the time of the start of the grant, the applicant cannot hold the title of Associate Professor or higher.

2. The project must be bladder cancer-specific (including upper tract urothelial carcinoma).
3. Applicant must be from a US or Canadian sponsoring academic, non-profit or governmental institution. Proof of permanent resident status or a valid work visa is required if the applicant is not an American or a Canadian citizen.
4. Applicant must have a mentor within or approved by the sponsoring institution. The mentor must assume responsibility for the overall conduct of the project, ensure protected research time and provide guidance for the research. The sponsoring institution must ensure institutional support for the research. Although mentors who have specific knowledge and experience in bladder cancer are encouraged, in instances where the mentor lacks bladder cancer experience, additional collaborator support from experts in the bladder cancer field are strongly advised. The applicant can have collaborators from outside institutions. Applicant must submit a letter of approval from their institution should they wish to have a mentor from an outside institution.
5. BCAN will not discriminate on the basis of gender, race, ethnicity, creed, religion, sexual orientation, disability, nationality, age or any other factor irrelevant to the quality of the application.
6. Applicant should include research milestones expected to be attained by the conclusion of the grant.
7. Prior BCAN Young Investigator Award winners are not eligible to apply for this award.
8. Applicant may not have other funding with significant scientific overlap.
9. BCAN will accept only one proposal from each applicant per announcement.

**Application Instructions:**

BCAN requires applicants to submit an online application using ProposalCentral. The online application is available here:

<https://proposalcentral.com/ProposalGI.asp?SectionID=6894&ProposalID=-1>

Inquiries or technical issues regarding ProposalCentral and the online application process should be directed to customer support at: Phone: 703-964-5840, Toll-free phone: 1-800-875-2562, Email: [pcsupport@altum.com](mailto:pcsupport@altum.com)

Live customer support is only available from 9am – 5pm Eastern time.

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to Bernadette Fitzsimmons or Rebecca Johnson at BCAN at 301-215-9099, or by email at [bfitzsimmons@bcan.org](mailto:bfitzsimmons@bcan.org), [rjohnson@bcan.org](mailto:rjohnson@bcan.org) or [grants@bcan.org](mailto:grants@bcan.org).

### **Application Components:**

The following information is required to submit a complete application. Numbers correspond to the application sections found on the left side of the ProposalCentral website.

#### **1. Project & Funding Information**

#### **2. Download Templates & Instructions:** Guidelines and all templates can be downloaded from this page.

- a. You must download and complete the following templates: Research Proposal, Training and Environment Summary, References, Personal Statement, Applicant Biosketch, Mentor's Biographical Sketch, and Letters of Recommendation.
- b. Use word processing software to complete the templates and then convert to PDF format.
- c. Completed templates must be uploaded in section II Application Attachments.

#### **3. Enable Other Users to Access This Proposal**

#### **4. Applicant Information**

Please be prepared to submit your ORCID number in your application.

#### **5. Institutional and Signing Official Information**

#### **6. Mentor & Key Personnel Information**

#### **7. Abstracts & Key Words**

- a. **Lay abstract (2000 characters):** Describe the project in a way that will be understood by people who do not have scientific or medical backgrounds. The abstract should clearly describe the scientific objectives and rationale of the proposal and should avoid technical and scientific terms when possible. The lay abstract should not duplicate the technical abstract. If the proposal is selected to receive an award, BCAN may use this information in press releases, Award announcements and to provide information to the general public regarding its Awards program. A statement regarding the applicability of the research to patients with bladder cancer is required.
- b. **Technical abstract (2000 characters):** The technical abstract should provide a clear and concise overview of the proposed work, including the background,

objective or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study, and study design.

8. **Budget Period Detail:** Please enter all budget information here for the project. See instructions under section 9: Budget Summary & Justification.
9. **Budget Summary & Justification (5000 characters):** Please use the budget template in ProposalCentral. No more than 10% of the budget may be used for salary support for the principal investigator including fringe benefits. Please include the percentage effort for the amount of work time that will be devoted to this project. There is no minimum effort percentage, but time commitment to the project will be considered in evaluating the application. Salary support for other research personnel must be specified in the budget template. Up to \$2,000 should be allotted specifically for the applicant's travel to the annual BCAN Think Tank meeting and/or for any other travel essential to conducting the study. No portion of the Award is to be used for indirect costs to the sponsoring institution (e.g. overhead/administrative). The Award will not support the purchase of capital equipment.

## 10. Organization Assurances

## 11. Application Attachments

Formatting Instructions:

- Paper Size: 8.5" x 11"
- Margins: at least 1/2" all sides.
- Font: Arial or Helvetica at least 11pt (or larger).

Using the templates where provided, prepare and upload the following documents into your application in portable document format (PDF):

- a. **Research Proposal (4 pages):** A one (1) year research proposal of no greater than four (4) pages is required. Applicants must include a description of how this research may benefit patients with bladder cancer and must describe the specific elements of the study design and approach that are patient-centered. The four-page limit applies only to the proposal and not to references, CV, or other supplemental information. Key sections to be included are: Title, Hypothesis and Specific Aims, Background, Preliminary Data if available (optional), Research Design and Methods, and a brief Summary with Timeline and Milestones.
- b. **References.** There is no page limit for this section. Please use single spaced, 11-point font for this section.
- c. **Patient Advocate Form (1 page):** Applications will be reviewed by a patient advocate to evaluate how well the applicant explains the potential impact of the proposal. The applicant should address the following three questions to detail

the relevance of the proposal to bladder cancer patients, caregivers, or other stakeholders and the focus of the proposed work on patient-centered care. The response should be written in a way that will be understood by people who do not have a scientific or a medical background.

- Describe the patient-centered problem, evidence gap and/or specific health decision being addressed, its scope, and the significance of this research for patients with bladder cancer. How will the results of this research improve outcomes that bladder cancer patients and other stakeholders care about (e.g., survival, functioning, symptoms, quality of life) and that inform an identified healthcare decision?
  - If the study is successful, what are the next steps to move the research into clinical practice?
  - Has the applicant engaged patient advocates and relevant stakeholders in the design, selection of outcomes and implementation of this study? If not, does the applicant need assistance from BCAN in identifying patients advocates to consult on their work?
- d. **Personal statement (1 page):** This section is limited to one page and should describe the applicant's career development plan, including:
- Impact of the Award on advancing the applicant's career in academia-based bladder cancer and/or upper tract urothelial cancer research.
  - The applicant's role in developing and implementing the proposed research study.
  - Other funding agencies/organizations where this research proposal was or will be submitted. If none, please indicate N/A.
- e. **Training and environment summary (1 page):** This section should provide an accurate representation of the time commitment that will be dedicated to the proposed project and should provide a detailed description of the applicant's non-research responsibilities during this period. The time commitment described should also be reflected in the supporting mentor letter that will accompany this application. Additional information regarding resources available to the applicant to successfully complete the proposed project should be included.
- f. **Applicant's biographical sketch:** Use the NIH form PHS 398, available on the [NIH website](#). Adhere to the NIH page limit.
- g. **Mentor's biographical sketch:** Use the NIH form PHS 398, available on the [NIH website](#). Adhere to the NIH page limit.
- h. **Two letters of recommendation:**
- **Primary mentor letter** that emphasizes the applicant's potential for independence in an academic research setting. The letter should also describe mentoring experience, time protection for the applicant, and a

commitment to provide resources and mentoring for the applicant for the duration of the Award as related to this project.

- **Institution letter from Department Chair, Dean or Cancer Center Director.** This letter should guarantee a specific time effort dedicated to this project, mechanisms by which the applicant's time will be protected from other obligations, and a commitment to provide resources to support the applicant's research proposal.
- i. **Supplemental Materials (optional):** Supplemental material may be uploaded ONLY to include letters from collaborators and IRB/IACUC/IND approvals if applicable and already received. Do NOT include figures or submit reprints of articles with this application. Additional letters of recommendation may also be uploaded.

**12. Validate:** Validate the application on ProposalCentral. This is an essential step. An application that has not been validated cannot be submitted. "Validate" checks for required data and required attachments. You will not be able to submit if all the required data and attachments have not been provided.

**13. Signatures page:** The applicant, mentor, and institutional signing official, must electronically sign this page in ProposalCentral. The application will be considered incomplete if this page is not complete. BCAN is no longer requiring an ink signature for submission. You can print signature pages as a way to save or keep a copy of your application. You do not need to upload anything here.

**14. Submit:** After successfully passing the validate check and passing the application attachments check, click the "**Submit**" link. An email will be sent to you confirming your submission.

- a. Once your application is submitted you may view it by accessing the "Submitted" link under the "Manage Proposals" tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the application to see the updated status.

There will be no exceptions to the **deadline of Tuesday, February 22, 2022 at 5:00 PM U.S. Eastern Time** to submit your application.

### **Evaluation Process and Criteria**

Interested applicants must submit an application by **5:00 PM (EST) on Tuesday, February 22, 2022**. The award decision will be announced by June 2022. The 2022 Young Investigator Award will start in July, 2022.

Applications will be evaluated by a Scientific Review Group comprised of experts respected for their own accomplishments in genitourinary (and specifically, bladder/upper tract urothelial) cancer research and as leaders in the field, as well as patient advocates from BCAN's research advocate program. The Scientific Review Group will review and score the applications based on the merits of the research proposals. The Award review process is based on the peer review system utilized by the National Institutes of Health (NIH). Research projects are scored individually by members of the review panel and scores are added together to determine the final ranking of each proposal. Any reviewer with a conflict of interest will be excused from discussing and voting on a specific application.

The Chair of the Scientific Review Group will present the highest ranked proposals to the Bladder Cancer Research Network (BCRN) Management Committee (comprised of members of BCAN's Scientific Advisory Board and patient advocates), which will review the ranking of the top applications based solely on those scores and recommend the final Award decision, based on all included criteria specified in the RFA, for approval by the BCAN Board of Directors. Any member of the Management Committee or the BCAN Board of Directors with a conflict of interest is excused from voting on the Award decisions.

Evaluation of the proposals will include consideration of the following criteria at minimum:

1. Merit of the research plan and objectives
2. Degree of patient stakeholder/advocate involvement in the design and implementation of the study and evidence of the project's feasibility, acceptability, and relevance to bladder cancer patients
3. Applicant's qualifications
4. Ability of primary mentor to provide appropriate guidance during the award period and demonstration that there are adequate resources available to the applicant to support the research project
5. Appropriateness of budget to completing the research plan during the grant period
6. Optional: Project's relevance to patient-prioritized research questions from the BCAN PSN

### **Terms of Award**

Payments will be made to the comptroller or to the designated financial officer of the sponsoring institution which shall then disburse the funds to the individual Award recipient. The Award start will be in July 2022. The Award recipient and the sponsoring institution shall pay at their own costs all taxes and impositions in connection with the Award. The Award does not create an employer-employee relationship between the Award recipient and BCAN. BCAN does not assume any legal responsibility or obligation for the conduct or acts of the grant recipient, the mentor, or the sponsoring institution.

Applications involving animals and/or human participants must receive approval from their Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB), respectively. Documentation of IACUC and/or IRB approval must be provided to BCAN prior to distribution of the Award. Applications involving an Investigational New Drug (IND) must receive approval from their IRB. Documentation of IND approval must be provided to BCAN prior to distribution of the Award.

Any changes to the specific aims or major changes in research design must be communicated to BCAN in writing prior to implementation of such changes. Examples of a major change in research design include, but are not limited to, studying a different patient population or therapeutic than originally proposed.

At the conclusion of the Award period, the Award recipient must complete a final report summarizing the research conducted, and any plans to continue the research beyond the Award period.

Publications, research talks, and poster presentations based on any study or research done with the support of the Award should acknowledge the support of BCAN throughout and following the Award period. Reprints of such publications or abstracts should be sent to BCAN.

The Award recipient will be expected to present research results at the conclusion of the Award at BCAN's Annual Bladder Cancer Think Tank meeting in August 2023.

The Award recipient may be asked to complete brief Award outcome reports for BCAN detailing any publications, funding awards, collaborations or other outcomes resulting from this Award for a period of three years after Award completion. The Award recipient understands that this reporting obligation survives the Award period.

In the event the Award recipient's research is substantively delayed due to unforeseen circumstances, or the applicant is unable to complete the project, the Award recipient and/or sponsoring institution is responsible for notifying BCAN as soon as possible to discuss next steps. In the event no mutually agreeable mitigation strategy is feasible that would allow for completion of the project and the award is terminated, the unused portion of Award funds must be returned to BCAN by the sponsoring institution within 30 days of the date of termination.





## **Appendix A| OPTIONAL – BCAN Patient Survey Network (PSN) Research Questions Prioritized by the Patient Community**

For patients with non-muscle-invasive bladder cancer:

1. What are the best treatments for patients whose cancer returns or worsens after BCG treatment?
2. What are the best biomarkers for predicting response to bladder treatments (intravesical therapy with drugs like BCG and mitomycin C)?
3. What are the best ways to decrease pain and discomfort from cystoscopy and procedures such as placing a catheter in the bladder?
4. What are the best ways to increase quit rates among patients who are smoking at the time of a bladder cancer diagnosis?
5. What is the effect of diet or lifestyle changes on bladder cancer incidence, severity, or treatment success?
6. What is the comparative effectiveness of different bladder treatments for patients whose bladder cancer returns after BCG treatment?

For patients with muscle-invasive non-metastatic bladder cancer:

1. How does a patient with invasive bladder cancer choose between preserving the bladder (with radiation and chemotherapy) and removing the bladder (radical cystectomy)?
2. How does a patient undergoing bladder removal (radical cystectomy) choose between different urinary diversions (such as ileal conduit and neobladder)?
3. Which patients benefit most from chemotherapy before bladder removal?
4. What recovery programs best improve sexual health for patients who undergo treatment for invasive bladder cancer?
5. What is the effect of diet or lifestyle changes on bladder cancer severity, or treatment success?
6. How do we improve patient education about expectations for recovery and treatment success after radical cystectomy?

For patients with metastatic or advanced bladder cancer:

1. How do new treatments for metastatic bladder cancer compare to others?
2. In what order should treatments be given for patients with metastatic bladder cancer?
3. What are the best ways for a patient to find out about new clinical trials for metastatic bladder cancer?
4. How can caregivers of patients with metastatic bladder cancer reduce their burdens?
5. What is the comparative effectiveness of different timing of initiation of palliative care or hospice?