



## **2021 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 judged 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**

1. At the time of submission, the applicant must be within six years following 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.

2. The project must be bladder cancer-specific (including upper tract urothelial carcinoma).

3. Applicant must be from a US or Canadian sponsoring academic, nonprofit or governmental institution. Proof of permanent resident status or a valid work visa is required if the applicant is not an American or Canadian citizen.

4. Applicant must have a mentor within or approved by the sponsoring institution. The mentor must assume responsibility, 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. Applications involving human participants must receive approval from their Institutional Review Board (IRB). Documentation of IRB approval must be provided to BCAN prior to distribution of the Award.

7. Applications should include research milestones for the conclusion of the grant.

8. Prior BCAN Young Investigator Award winners are not eligible to apply for this award.

9. BCAN will accept only one proposal from each applicant.

### **Application Components:**

**1. Assurances page.** The applicant, mentor, and institutional signing official must sign and date the Assurances page. The application is considered incomplete if this page is not complete. Note: proposalCENTRAL creates a signature page at the end of the proposal process. This can be retained for your files. You do not need signatures for the proposalCENTRAL generated page. Please be prepared to submit your [ORCID](#) number in your application.

**2. Lay abstract (2000 characters).** The lay abstract should communicate the purpose of and rationale for the study to the nonscientific community. It should be composed with the objective of making the scientific objectives and rationale of the proposal understandable to nonscientifically trained readers 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.

**3. 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.

**4. 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. 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, Research Design and Methods, and a brief Summary with Timeline and Milestones.

**5. Patient Advocate Form (1 page):** Applications will be reviewed by a patient advocate based on 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 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 scientific or medical background.

1. Describe the patient-centered problem being addressed, its scope, and the significance of this research for patients with bladder cancer. How will the results of this research improve quality of life for bladder cancer patients?
2. If the study is successful, what are the next steps to move the research into clinical practice?
3. Has the applicant engaged patient advocates and relevant stakeholders in the design and implementation of this study? If not, does the applicant need assistance from BCAN in identifying patients advocates to consult on their work?

**6. References.** There is no page limit for this section. Please use single spaced, 10-point font for this section.

**7. Budget and budget justification (1 page).** 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. No portion of the Award is to be used for indirect costs to the sponsoring institution (e.g. overhead/administrative costs). The Award will not support the purchase of capital equipment. Limit the budget justification to 5000 characters, highlighting key elements in the budget.

**8. Personal statement (1 page).** This section is limited to one page and should describe the applicant's career development plan, including how the applicant will use the Award to advance her/his career in academia-based bladder cancer research.

**9. Training and environment summary (limit 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 be also 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.

**10. Applicant's biographical sketch (limit 5 pages).** Use the NIH form PHS 398, available on the [NIH website](#).

**11. Mentor's biographical sketch (limit 5 pages).** Use the NIH form PHS 398, available on the [NIH website](#).

**12. Two letters of recommendation.**

1. Primary mentor letter that emphasizes the applicant's potential for independence in an academic research setting. The letter should also describe mentoring experience, plan for 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.

2. 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.

**13. Supplemental material.** Please use this section ONLY to include letters from collaborators, letters of support from a patient advocate, and IRB/IACUC/IND approval. Do NOT submit reprints of articles with this application. Additional letters of recommendation may be included here.

## **Evaluation Process and Criteria**

Interested applicants must submit an application by **5:00 PM (EST) on Tuesday, February 16, 2021**. The award decision will be announced by June 2021. The 2021 Young Investigator Award will start on July 15, 2021.

Evaluation of the applications will be by a Scientific Review Group comprised of experts respected for their own accomplishments in genitourinary 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 each medical expert and scores are added together to determine the final ranking of each proposal. Any reviewer with a conflict of interest will be excused from 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, but not be limited to the following:

1. Merit of the research plan and objectives
2. Project's relevance to patient-prioritized research questions from the BCAN PSN
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

## **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 date will be July 15, 2021. 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.

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. 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 2022.

In the event the Award recipient's research is interrupted due to an incapacitating physical or mental illness or death, the Award will be terminated, and the unused portion of the 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?