Career Development Award 2024

PURPOSE OF AWARD

This Award is intended to support investigators who have received their initial faculty appointment to establish an independent bladder cancer (including upper tract disease) research program and successful career path. This three-year grant, totaling $250,000, is designed for junior investigators yet to secure their first significant research funding (NIH R01 or equivalent). Training grants and other mentor-linked funding are not considered independent funding. The research proposed for funding may be translational, clinical (including clinical trials), or epidemiological, must have direct applicability and relevance to bladder cancer and/or upper tract urothelial cancer, and must demonstrate the likelihood of translating new concepts into clinical practice. Project proposals should have measurable outcomes during the three-year grant period and include research milestones for the conclusion of the grant.

APPLICATION DEADLINE

Friday, October 11th, 2024, at 5:00 PM U.S. Eastern Time

DECISION ANNOUNCED

Mid-late January 2025

EARLIEST GRANT START DATE

March 3, 2025

ELIGIBILITY

Note: While applicants are welcome to include Co-Investigators in their Career Development Award proposal, this mechanism does not allow for Co-Principal Investigators.

1. At the time of submission, the applicant must have a doctoral degree (e.g., MD, DO, DDS, Ph.D., DNP, DSW, PharmD, PsyD, DVM, or equivalent) in the biomedical sciences or a field applicable to health science research and may not currently be a candidate for a further doctoral degree. The applicant must be an assistant professor, instructor, research assistant professor, or equivalent within seven years of their first full-time faculty appointment. At the time of application submission, the applicant cannot hold the associate or full professor title. Parental, medical, or other well-justified

leave for personal or family situations of generally less than 12 months duration is not included in the 7-year eligibility limit.

2. The 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 a Canadian citizen.

3. The applicant must be able to commit at least 50% of full-time effort in research (applies to total research, not just the proposed project) during the Award period.

4. The sponsoring institution must ensure institutional support for the applicant's research program and career advancement.

5. The applicant cannot currently or have previously served as a principal investigator on major independent research awards or grants (e.g., NIH R01 or equivalent). Applicants who are/were principal investigators on major grants are considered to have already received funding to catalyze their careers and are not eligible to apply. Training grants and other mentor-linked funding are not regarded as independent funding.

6. The applicant may not have another award with significant scientific overlap. Additionally, if an applicant receives notice of funding from another funding agency for a proposal with significant scientific overlap following submission of their CDA application or following award notice, the applicant will have to decide between the awards. BCAN will not allow the applicant to modify the aims for either award.

7. Eligible applicants are allowed to hold only one active grant from BCAN at a time.

8. Applicants must be up-to-date and in compliance with all requirements (e.g., progress reports, final reports) of any past grants from BCAN.

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

EVALUATION PROCESS AND CRITERIA

BCAN will not discriminate based on gender, race, ethnicity, creed, religion, sexual orientation, disability, nationality, age, or any other factor irrelevant to the quality of the application. The applications will be evaluated by a Scientific Review Group (SRG) comprised of medical and scientific experts respected for their accomplishments in genitourinary cancer research and as leaders in the field, as well as patient advocates from BCAN's research advocate program. The SRG will review and score the applications based on the below criteria. The Award review process is based on the same peer review system utilized by the National Institutes of Health (NIH). All applications will initially be reviewed by three scientific reviewers; the top scoring applications will advance to the second stage of review to be reviewed by a biostatistician reviewer and patient advocate reviewer. The applications with the top scores following the biostatistician and patient advocate reviews will then advance to the SRG discussion where they will receive a new overall score. Scoring of research projects is done 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 is excused from discussing and voting on a specific application.

Following the SRG discussion, the SRG Chair will present the highest-ranked proposals to the Bladder Cancer Research Network (BCRN) Management Committee (comprised of members of BCAN's Scientific Advisory Board (SAB), as well as patient advocates), which will accept the scientific merit scores. The BCRN will review the ranking of the top applications based solely on those scores and recommend the final Award decisions, based on all included criteria specified in the Award Guidelines, for approval by the BCAN Board of Directors. Any member of the BCRN 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. **Responsiveness to the Award Guidelines:** Project's relevance to the prevention, detection, diagnosis, and/or treatment of bladder cancer and/or upper tract urothelial cancer. Is the proposed research translational, clinical (including clinical trials), or epidemiological in nature? Does it directly demonstrate the likelihood of translating new concepts into clinical practice?
2. **Merit of the Research Plan and Objectives**: Is the conceptual approach or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the project's aims? Does the applicant acknowledge potential problem areas and consider alternative tactics?
3. **Feasibility, Acceptability, and Relevance to Bladder Cancer Patients:** Can the project be completed as proposed and in the allotted timeframe? Is it scientifically and logistically feasible? Are the milestones appropriate? Does the proposal demonstrate the research question and steps needed for implementation are acceptable and important to bladder cancer patients? Does the application demonstrate the significance of the research to bladder cancer patients? Was there patient engagement in the study's design, and is there proposed patient engagement in the study? Note: BCAN may be able to assist in the identification of a patient advocate if needed. Any requests for this type of support must be made by Friday, September 20th, 2024.
4. **Investigator:** Is the candidate appropriately trained and well-suited for the proposed work? Is the work proposed appropriate to the experience level of the candidate and study team? Does the candidate demonstrate a desire to pursue a research career in bladder cancer and are they well-poised to succeed as an independent investigator?
5. **Environment:** Does the application demonstrate that there are adequate institutional facilities and resources available to the applicant to support the research project? Is there evidence of institutional support?
6. **Budget:** Is the budget appropriate and justified based on the work proposed in the research plan during the grant period?

APPLICATION INSTRUCTIONS

APPLICATION PROCEDURES

BCAN requires applicants to submit an online application using ProposalCentral. The online application is available here: https://proposalcentral.com/ProposalGI.asp?SectionID=10647&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. Live customer support is only available from 9:00 AM – 5:00 PM EST.

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to Rebecca Johnson (rjohnson@bcan.org), or Anne Collins (acollins@bcan.org) or to BCAN (grants@bcan.org).

Exceptions will not be made to the application deadline of Friday, October 11th, 2024, at 5:00 PM U.S. Eastern Time. BCAN strongly suggests beginning application submission well before the deadline to allow time for submission and electronic signatures.

Applicants experiencing technical difficulties must contact ProposalCentral well before the 5:00 PM EST deadline. Please do not contact BCAN for technical assistance.

APPLICATION COMPONENTS

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

Please ensure that your application and ALL attachments conform to the instructions outlined in these guidelines and the related templates, including formatting (e.g., page limits, section headers, etc.) and required content. Additionally, please make certain that your application contains ALL the required components and attachments. Applications that do not contain all the required components and attachments may be administratively withdrawn and will not advance for review.

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, Facilities, References, Personal Statement, Training and Environment Summary, Patient Advocate Form, Applicant Biosketch, and Biostatistical Plan. These are not required for Co-Investigators.
    b. All completed templates must be uploaded in PDF format.
    c. Completed templates must be uploaded in Section 11: Application Attachments.

3. **Enable Other Users to Access this Proposal:** Please ensure the institutional signing official is added to allow them to sign the Signatures Page before submission. You may optionally add other contacts if you would like to enable access.

4. **Applicant Information**

5. **Institutional and Signing Official Information**

6. **Key Personnel Information:** Please include pertinent collaborators' information (e.g., Co-Investigators, etc.).

7. **Abstracts and Keywords**
    a. **Lay Abstract (2000 characters):** Describe the work in a way that will be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. A statement regarding the research's applicability to bladder cancer patients is required. It should not include confidential information. BCAN may use this information in press releases, Award announcements and to provide information to the general public regarding its Awards program.
    b. **Technical Abstract (2000 characters):** The technical abstract should specify the relevant background, research question, hypothesis, aims of the project, and methodologies. A statement regarding the research's applicability to bladder cancer patients is required.

8. **Budget Period Detail:** Enter all budget information for the project here. See instructions under Section 9: Budget Summary & Justification.

9. **Budget Summary and Justification (5000 characters):** Please use the budget template in ProposalCentral. The total Award amount is $250,000, payable over three years in amounts specified in the proposed budget for each year. During the Award period, at least 80% of the yearly budget must be expended by the end of each reporting year as a condition of approval for new funds.
    - At least 90% of each year's budget should support costs directly related to the research project, such as investigator salary support, personnel salary, supplies, equipment, and other expenses. Salary limits will be equivalent to the NIH applicable limit. Budgeted items must be consistent with available institutional facilities and resources.
    - Patient care costs that are reimbursable by a third-party payor, professional membership dues, tuition fees, and other fees for academic courses are unallowable.
    - Up to $2,000 per year should be explicitly allotted for the applicant's travel to the annual BCAN Think Tank meeting and any other travel essential to conducting the study.
    - Indirect costs: Up to 7% per year may be applied to overhead or facilities and administrative costs of the applicant's institution in administering the research project.

10. **Organization Assurances**

11. **Application Attachments**

Formatting instructions: Must be in English, single-spaced.
- Paper Size: 8.5" x 11".
- Margins: at least 1/2" on all sides.
- Font: Arial or Helvetica at least 11pt (or larger).

A. Research Proposal (Required; Limited to 5 pages, including figures and tables): Note the Biostatistical Plan should not be included in this section – see item #11.B below. The information must be presented in this order and must consist of these subheadings:
- Title of Research Project

- Introductory Statement: Research Question, Background, and Rationale. Clearly state the research question. Explain the importance of the problem or critical barrier to progress in the bladder cancer field that the proposed project addresses and how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the proposed aims are achieved.
- Hypothesis and Specific Aims
- Research Design and Methods: Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Describe the overall study design or strategy, the methodology, and planned analyses to be used to accomplish the specific aims of the project. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility and address the management of any high-risk aspects of the proposed work.
- Milestone Timetable (setting forth the steps needed to accomplish each aim and the estimated time required to complete each step). Appropriate detail should be included to assure a reviewer that the applicant's project is feasible in the timeframe of the grant.

B. Biostatistical Plan (**Required – limited to 1 page):** A biostatistician will review applications. A detailed statistical plan is required for all applications and is limited to one typewritten, single-spaced page. For clinical and in-vivo studies, this section should include the primary objective/hypothesis and endpoint of the study, a description of the experimental design and study groups that will be compared, a justification of the proposed study sample size, detailed procedures for data analysis, and appropriate statistical considerations. A reasonable sample size justification will include all parameters required to compute the sample size: the effect size, power, and type I error rates for each aim. When relevant to the project, it will also state median follow-up, prevalence of mutations in a given population, accrual rate, and estimated percentage of participant dropout. Laboratory-based in vitro research proposals should also include the primary objective/hypothesis and the primary endpoint of the study, procedures for data analysis, and appropriate statistical details that describe the summary measures that will be used to meet the objectives of the study. The applicant should work with a biostatistician to develop the application. If statistics are not applicable to the project, the applicant should upload a document stating that "Biostatistics are not applicable", and the reviewers will evaluate the project accordingly.

C. Facilities (Required; Limited to 3 pages): Describe the research facilities, resources, and equipment available to the applicant to implement the proposed research program successfully.

D. References (Required): There is no page limit for this section. Please use single-spaced, 11-point font for this section.

E. Personal statement (Required; Limited to 1 page): Describe the applicant's career development plan, including:

- Impact of Award on applicant's career, including the applicant's career goals.
- Percentage of time the applicant will spend on total research activities.
- The applicant's role in developing and implementing the proposed research study.

- Sources of salary support for the applicant.
- The translational or clinical potential of this research project.
- List other funding agencies/organizations where this research proposal was or will be submitted. If none, please indicate N/A.

F. Training and Environment Summary (Required; Limited to 1 page): This section should accurately represent the time commitment that will be dedicated to the proposed project and a detailed description of the applicant's non-research responsibilities during this period. The time commitment described should also be reflected in the application's supporting sponsor letter.

G. Patient Advocate Form (Required; Limited to 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 proposal's relevance to bladder cancer patients and the focus of the proposed work on patient-centered care. The response should be written by the applicant in a way that will be understood by people who do not have a scientific or medical background.

- Describe the problem being addressed, its scope, and the significance of this research for bladder cancer patients.
- Describe any steps taken to ensure the research question and steps needed for implementation are acceptable to bladder cancer patients as well as any planned patient engagement during the conduct of the study.
- If the study is successful, what are the next steps to move the research into clinical practice?

H. Applicant's Biographical Sketch (Required; adhere to NIH page limits): Use the template found in Section 2: Download Templates & Instructions.

I. Publications (optional): Up to two prior publications that highlight the applicant's experience and qualifications may be included. The applicant must be a co-author on these publications.

J. Sponsor Letter (Required): The sponsor must attest to the institutional support for the applicant. The sponsor can be the department head, chief of service, or program chair. This letter should include the following information:

- Confirmation that the applicant is within the first 7 years of their first full-time, faculty appointment at the time of application submission.
- Description of the applicant's position.
- Description of the sponsoring institution's support for the applicant's research and clinical activities.
- Description of the potential of the applicant to become a leader in bladder cancer research and/or treatment.
- Future plans for the applicant's career development at the sponsoring institution.
- Description of how the applicant's time will be divided among research and other responsibilities to the sponsoring institution with a minimum of 50% protected research time.

K. **Patient Advocate Letter of Support (Required):** At least one letter of support from a patient advocate is required. The letter should attest to the importance of the research question to patients and that the steps required for study implementation are acceptable to bladder cancer patients. The letter should also describe any patient engagement or input in the design of the study and proposed patient engagement in the conduct of the study. Note: BCAN may be able to assist in the identification of a patient advocate if needed. Any requests for this type of support must be made by Friday, September 20th, 2024.

L. **Additional Letters of Support (optional)**

M. **Supplemental Material:** Please use this section ONLY to include letters from collaborators, additional letters of recommendation, and IRB/IACUC/IND approval. Do NOT include figures or submit reprints of articles with this application.

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 and institutional signing official must electronically sign this page in ProposalCentral. Co-Investigators do not need to sign. 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.

CHANGES TO YOUR APPLICATION

Withdrawal of Application: Please advise BCAN promptly, in writing, should you decide to withdraw your application for any reason. Your letter or email should include your name, the title of the proposal, and the reason for withdrawal.

Change of Address: Notify BCAN in writing of any changes of address, email, or phone number, following the submission of an application. Include your name and application number. The email address provided with your application will be used for all official communication about your submission, including the recipient selection results. Please keep your email address up to date.

TERMS OF AWARD

Payments will be made annually to the comptroller or to the designated financial officer of the sponsoring institution which shall then disburse the funds to the individual Award recipient. BCAN considers the start of the grant to occur at the time of grant activation and disbursement of funds and aligns progress reports deadlines accordingly. The award start date will be no earlier than March 3rd, 2025. Any activities that occur from the time of grant activation through the end of the first reporting year, including start-up activities, should be reported on in the first progress report period. 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 Award 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 and yearly during the funding period. 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 and for each year of funding.

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 first 12 months of the Award period, the Award recipient shall submit a written summary documenting in reasonable detail his/her progress in completing the research project. All report templates will be provided by BCAN. Funding for the second 12 months is dependent on submission of this progress report and review and approval by BCAN. At the conclusion of the second 12 months of the Award period, the Award recipient shall submit a written summary documenting in reasonable detail his/her progress in completing the research project. Funding for the final 12 months is dependent on submission of this progress report and review and approval by BCAN.

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 attend BCAN's Bladder Cancer Think Tank during the Award term and is required to present research results at the 2028 Bladder Cancer Think Tank Meeting.

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 recipient 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.