

AMERICAN UROLOGICAL ASSOCIATION PROGRAM ANNOUNCEMENT

2025 AUA Data Research Program

IMPORTANT DATES

Letter of Intent Submission Opens: May 1, 2024

Letter of Intent Deadline: June 23, 2024, 11:59 p.m. EST

Invitation to Submit Full Application: August 1, 2024

Full Application Deadline: September 30, 2024, 11:59 p.m. EST

Award Notification: December 6, 2024

Award Term: January 1, 2025 – December 31, 2025

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I. FUNDING OPPORTUNITY DESCRIPTION

A. AMERICAN UROLOGICAL ASSOCIATION DATA RESEARCH PROGRAM

The mission of the American Urological Association Education and Research corporation ("AUA") is to improve practice and patient care by providing affordable quality urologic education. The AUA is a leader in helping to identify gaps in knowledge and communicating urology research needs to key stakeholders in the Urology community. The AUA, with the support of the AUA Data Committee, has been building a comprehensive data repository in urology, which would allow researchers to conduct studies from clinical, workforce, and policy perspectives. Having recognized a major need to support the future of urologic research, the AUA relaunched the AUA Data Research Program (formerly AUA Data Grants) with the aim of connecting the urology research community to vast AUA resources. The AUA Data Research Program encourages the broad use of AUA data, with the assistance of AUA Statisticians and the AUA Data Committee.

The AUA Data Research Program is also intended to stimulate the use of AUA data sources for knowledge generation and dissemination. The AUA Annual Census and the AUA Quality (AQUA) Registry are invaluable data sources for urology clinical and workforce research initiatives and will be the primary data sources for the AUA Data Research Program. AUA Data to be used in the Program may include:

- Practice, provider, and patient data in the AQUA Registry.
- Disease-specific patient cohorts with well-documented information on initial and follow-up diagnoses, treatments, and outcomes.
- AUA Annual Census datasets from 2014 to the most recent year.

The AUA Data Research Program is administered by the AUA Data Management and Statistical Analysis Department, under the guidance of the AUA Data Committee. The AUA is committed to promoting diversity within the urologic research workforce. The AUA does not discriminate as to age, race, color, gender, religion, sexual orientation, disability, citizenship, or national origin in the employment and promotion of staff or in the selection of participants in the AUA Data Research Program.

B. AWARD INFORMATION

Urologic research is critically important to advancing patient care and requires a diverse array of talented, dedicated individuals. AUA Data-focused research has the potential to address key knowledge gaps related to urology care and workforce development, and to transform clinicians into physician scientists through exposure to diverse data sources, and the building of mentoring relationships with experts in the AUA Data Committee.

Through a Request for Proposal (RFP) process starting in May 2025, a total of six projects (two projects using AQUA Registry data and four using AUA Census data) will be selected and funded each year in the form of:

- Complimentary access to the Annual Census or the AQUA Registry data through AUA Statisticians.
- Full statistical analysis support (25 hours per Census project and 100 hours per AQUA project).
- Assistance with developing the methodology section for abstracts and publications.
- A \$2,000 stipend to cover the Recipient's (Principal Investigator's) costs for knowledge dissemination. Covered costs include travel to conferences and presentation/publication costs.

Applicants are encouraged to submit research proposals that address health care disparities in the field of urology, underrepresented populations, and current AUA policy and advocacy initiatives.

C. ELIGIBILITY INFORMATION

AUA Membership

All AUA members are eligible and encouraged to apply, including trainees, early-stage investigators, and providers/researchers of AQUA participating sites. One application per applicant as Principal Investigator is allowed during a competition year.

AUA member ID will be required during the application process and proof of current membership must be provided to the program administrators prior to the project launch. Additional information about AUA membership can be found at: https://www.auanet.org/membership.

Receipt of Previous Awards

Previous Data Research Program ("DRP") grant recipients (Principal Investigator or co-Investigator) are not eligible to re-apply as Principal Investigator or co-Investigator for the next 3 funding cycles following receipt of their award. For example, 2024 DRP recipients will not be eligible to re-apply until the 2028 DRP cycle.)

D. AVAILABLE DATA SOURCES

The AUA's mission to advance the science of urology through research is exemplified by the continuous expansion of the AUA Urology Data Repository. The repository is comprised of urology-related datasets that are well-documented, integrated, and readily available for research and insight generation. The AUA Quality (AQUA) Registry data and the AUA Annual Census are key components of the repository and invaluable data sources researchers can use within the AUA Data Research Program to conduct their research projects and develop abstracts and publications.

During the application process, applicants will be asked to designate which data source they will use for the research proposal. Applicants can explore the <u>data dictionaries</u> for the available AQUA data modules and the Census questions, and review the <u>data projects feasibility guide</u> for examples of projects that can or cannot be completed using the Census or AQUA data.

AUA Quality (AQUA) Registry

Developed by urologists for urologists, the AUA Quality (AQUA) Registry is a national Qualified Clinical Data Registry (QCDR) designed to measure, report and improve healthcare quality and patient outcomes. The Registry collects real-world data directly from urology practices' electronic health record (EHR) system to participate in quality improvement activities, contribute to national urology benchmarks, and access quality measures meaningful to urologists.

The AQUA Registry is a collection of over 214 practices spread across the United States and US territories. The Registry itself was started in 2014 and contains data from 2013 to 2024. Using data collected in the AQUA Registry, the AUA is developing data modules each centered on a major urologic condition, that include curated information on patient demographics, diagnoses, treatments, outcomes, as well as provider and practice information.

Applicants planning to use the AQUA Registry data for their proposals are encouraged to use the existing data modules to formulate their research questions and develop their research proposal. Urologic conditions not listed below (i.e., data modules not yet developed) may be considered if patients of interest and the associated procedures and outcomes are well-defined by ICD/CPT codes.

The five modules currently available for use in the AUA Data Research Program are:

- Overactive Bladder (OAB)
- Benign Prostatic Hyperplasia (BPH)
- Kidney and Ureteral Stones
- Male Stress Urinary Incontinence
- Erectile Dysfunction (ED)

AUA Annual Census

First launched in May 2014, the AUA Annual Census provides clinicians, policymakers, payers, and patients with important information about urologic providers' geographic distribution, demographic characteristics, education and training, and patterns of urology practice. It also identifies cross-sectional and longitudinal variations across the specialty nationwide. The Census is a specialty-wide survey of all members in the urology community across the globe. The AUA Census data is thus a great resource for urologic care researchers to conduct research and generate publications in the field of urology.

E. OVERLAP IN FUNDING

Being a current or previous recipient of a funding award from other organizations or government agencies does not disqualify application and participation in the AUA Data Research Program. Applicants are, however, required to report all previously received and active funding within their biosketch during the application process.

F. ALLOWABLE USE OF STIPEND

The intent of the AUA Data Research Program stipend is to provide minimally restricted support to the Recipient (Principal Investigator) to cover the costs of research dissemination for a selected AUA Data Research Program Research Project. Covered costs include travel to conferences (registration, lodging, flights, etc.), printing of posters and other materials, as well as presentation/publication costs.

The AUA Data Research Program stipend may not be used for institution indirect costs, applicant salary support, or costs related to any personnel other than the awardee (Principal Investigator).

G. DISTRIBUTION OF STIPEND

The AUA Data Research Program stipend will be paid directly to the Recipient (Principal Investigator) via wire transfer in one installment in July, contingent upon receipt of the mid-year progress report. The AUA does not withhold taxes from stipends (federal withholding, social security, local or state taxes, etc.). Taxes and other withholdings are the responsibility of the awardee.

H. RESTRICTIONS TO THE USE OF ARTIFICIAL INTELLIGENCE

The AUA prohibits the use of American Urological Association, Inc., American Urological Association Education and Research, Inc. and Urology Care Foundation content in third party applications, including artificial intelligence ("AI") technologies, such as large language models and generative AI.

AUA Data Research Program applicants are prohibited from using generative AI tools to draft their Letters of Intent (LOIs) and/or full applications.

AUA Data Research Program awardees are prohibited from using or uploading Data or other content accessed or generated through or for the purpose of this Program into external applications, bots, software, or websites, including those using artificial intelligence technologies and infrastructure, including deep learning, machine learning and large language models and generative AI. Prohibited content includes but is not limited to the Data, AUA website content, grant application materials, grant review and selection materials, patient-level, provider-level or practice summary Census or AQUA Registry data, research results, etc.

Generally, research conducted with AUA grant funds may not include, in whole or in part, any content, including tables or figures, generated by Artificial Intelligence.

II. APPLICATION REQUIREMENTS

A. GENERAL INFORMATION

The AUA Data Research Program application process consists of a letter of intent (LOI) followed by a full application. Applicants should review this Program Announcement in its entirety to understand and begin preparing the required components. Questions on eligibility, application materials, etc. should be directed to the program administrator via email at dataservices@auanet.org.

Applicants are responsible for composing, compiling, and submitting complete materials. It is the responsibility of the applicant to ensure that all required items are submitted in full electronically via the proposal submission system in advance of submission deadlines.

A letter of intent is required, and must be received by June 23, 2024, at 11:59 p.m. EST. The letter of intent undergoes administrative compliance review and is used to gauge applicant eligibility, document compliance, and prepare for peer review of full applications. Following administrative review, LOIs are reviewed by the AUA Data Research Program Scientific Review Panel for project feasibility, merit of the proposal, and potential impact in the field of urology. Submission of a letter of intent does not guarantee that applicants will be invited to submit a full application.

Only one letter of intent can be submitted per applicant and applicants are not bound to complete a full application upon submitting a letter of intent. Following administrative and scientific review, selected letter of intent submissions will receive access to the full application submission portal. Invitations to submit full applications will be sent to selected applicants on August 1, 2024, and the deadline to complete the full application is September 30, 2024, at 11:59 p.m. EST.

Full applications will be evaluated for overall impact and significance to the field of urology, innovation, approach, and Principal Investigator's credentials and experience. Following review and deliberation, applicants will be notified of funding decisions on December 6, 2024, and selected studies will begin in January 2025.

Electronic Submission

Applicants must submit all required documents electronically via ProposalCentral at https://proposalcentral.com/. Submission of materials via email, fax, or postal mail will not be accepted.

To prevent emails from ProposalCentral from being identified as spam, it is strongly recommended that applicants add pcsupport@altum.com to their address books or safe sender lists. Applicants requiring technical support related to the grant submission portal should contact ProposalCentral directly.

B. LETTER OF INTENT REQUIREMENTS

1. APPLICANT AND ELIGIBILTY INFORMATION

Applicant Information

The letter of intent should include the personal information, institution, and contact information of the Principal Investigator (PI) and all co-investigators.

Eligibility Information

Applicants will be required to provide their AUA ID number to confirm AUA membership. Applicants will need to specify if they or one of their co-investigators are a previous Data Research Program recipient, and if yes, specify the year they received the award.

2. PROJECT DESCRIPTION

Applicants will be required to provide a brief description of the project that reflects the key elements of the research proposal during the letter of intent submission process. Helpful Hint: the structure of the project description is modeled after a specific aims page.

The project description should contain the following elements:

Project Title (do not use all capital letters)

Provide a title for your proposed research project. The project title should paint a quick picture of the main focus and key ideas of your project.

Data Source

Specify whether your proposed project will be based on the AQUA Registry Data or the AUA Census Data. If using the AQUA Registry data, specify the data module or urologic condition you wish to study. If your project is based on the Census data, specify the Census year(s) and the question(s) you wish to study.

Project Significance/Background (2500-character limit)

Briefly introduce the problem to be addressed and provide a brief background. State the rationale of your research proposal.

Project Objective (500-character limit)

Discuss what you intend to accomplish, and provide specific, measurable outcomes.

Project Specific Aims/Approach (1500-character limit)

Provide specific aims and discuss what overall strategy and methodology you will use to accomplish your aims. Provide key steps to fulfill your research objectives. Specify which elements of the supporting data you plan to use. Discuss the methodology in enough details that reviewers can determine the feasibility of your proposed project.

Project Impact (500-character limit)

Discuss why the problem of interest is an important problem in urology, and how your research will potentially improve urology practice.

C. FULL APPLICATION REQUIREMENTS

1. APPLICANT BIOSKETCH

Applicants are required to submit an NIH-style biosketch with the **full application**, strictly limited to five pages, including descriptions of any research experience, pending or awarded grants, as well as research interests and career goals. A sample biosketch can be found at https://grants.nih.gov/grants/funding/2590/biosketchsample.pdf. Submissions that do not include the applicant's biosketch and/or documents that exceed the page limitations will be deemed noncompliant and will not advance for further review or receive consideration for an award.

2. RESEARCH PROJECT NARRATIVE

Applicants are required to submit a Research Project Narrative during submission of the **full application**. The research project narrative is strictly limited to four pages, inclusive of figures and tables, and must use the section headers in sequence as ordered below. Applications that exceed the page limitation will be deemed noncompliant and will not advance for further review. The project narrative must be submitted as one PDF document.

Project Narrative

- I. Research project title
- II. Research project summary/abstract (<350 words)
- III. Specific aims: The specific aims should (1) state concisely and realistically what the research project intends to accomplish and (2) should list measurable objectives for the proposed
- IV. Significance/impact and background:
 - What is the knowledge gap that your research project addresses? Describe the background literature.
 - What is your hypothesis?
 - Why is this topic important to the field of urology?
- V. Innovation:
 - How does your approach differ from current practice or knowledge?
 - How will it potentially improve urology practice or workforce?
- VI. Approach, implementation, and evaluation:
 - What is the overall strategy and methodology you will use to accomplish the specific aims of the research project? (Please describe design, sample, and procedure.)
 - How will data be analyzed and interpreted?

Describe the potential barriers to the project's success and any mitigation strategies.

VII. Sustainability and scalability:

- How will you demonstrate the success of your research project?
- How will you disseminate the knowledge learned?
- What are the next steps after the award period?

3. CITED REFERENCES

References should be in American Psychological Association (APA) format and uploaded in a pdf format. References cited page(s) and abbreviations/acronyms lists do not count against the page limit for the project narrative and are uploaded as separate documents in ProposalCentral.

D. FORMATTING GUIDELINES

Letter of Intent

The following guidelines are applicable to all documents submitted for the letter of intent. Applicants must follow the character limits.

Length: The Project Significance/Background is limited to 2500 characters. Project Objective has a 500character limit. Project Specific Aims/Approach is limited to 1500 characters, and Project Impact Is limited to 500 characters.

Full Application

The following guidelines are applicable to all documents submitted for the full application. All applications must be submitted in accordance with the requirements and instructions of the Program Announcement. Proposals must demonstrate high-impact objectives and hypotheses, rigorous research methods, appropriate timelines, and clearly-defined deliverables.

Length: The project narrative is limited to 4 pages. This limit does not include contact information, biographical sketches, references, or supporting documentation. Narratives exceeding 4 pages will not be considered. The project narrative must be submitted as one PDF document, exclusive of citations page(s), references, and lists of acronyms/abbreviations.

Style: Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 12 points, single spaced; margins must not be smaller than 0.5" on any side.

E. EXCLUSION CRITERIA

Applications violating any of the following conditions are deemed noncompliant and thus will not be advanced for further review and are ineligible for award consideration. Final determination is at the sole discretion of the AUA Data Research Program Scientific Review Panel.

- Noncompliance with formatting guidelines.
- Required elements of the project description not included in submission of the letter of intent.
- Applicant biosketch not included in submission materials for the full application.
- Required elements of the project narrative not included in submission materials for the full application.
- Letter of intent or full application materials received after the submission deadlines.

- Incomplete letter of intent or full applications that are missing required elements.
- Incomplete letter of intent or full applications not meeting administrative compliance review.
- Applicant and/or co-investigators have received a DRP grant within the past three (3) funding cycles.

III. LETTER OF INTENT AND FULL APPLICATION SUBMISSION INSTRUCTIONS

A. LETTER OF INTENT

After creating a ProposalCentral account and logging into the system, the applicant can locate the AUA Data Research Program by clicking on the "Grant Opportunities" tab and searching for the American Urological Association as the Grant Maker. The letter of intent can be accessed by clicking the "Apply Now" button. Letter of intent sections are listed below with additional guidance on how to complete each section. Applicants are responsible for ensuring the accuracy and completeness of all materials, that any materials or content were not generated in whole or in part by any Artificial Intelligence tool or program, and that materials are received in full before the letter of intent deadline.

1. Project Title

Provide a title for your project (do not use all capital letters)

2. Enable Other Users to Access this Proposal

This section enables applicants to give other users access to the letter of intent but is not required.

3. Applicant/Principal Investigator (PI) Information

Applicants will need to toggle between their "Professional Profile" in ProposalCentral and sections of the letter of intent to reference and complete the required information.

- a. Name (Last, First, Middle)
- b. Current position or title at applicant organization
- c. Applicant organization
- d. Academic credentials
- e. Contact information (address, email, phone)

4. Eligibility

- a. AUAID Applicants should enter their AUA member ID.
- b. Previous Data Research Program Awardee
- c. Year of previous Data Research Program award

5. Key Personnel (Optional)

Applicants have the option to identify up to 4 co-investigators on the proposed project. All co-investigators must be current members of the AUA.

- a. Are you submitting a LOI with a co-investigator?
- b. If yes, provide the following information for each co-investigator:

Co-investigator:

- i. Name (Last, First, Middle)
- ii. AUA ID
- iii. Current position or title at applicant organization

- iv. Applicant organization
- v. Academic credentials
- vi. Contact Information (address, phone, email)

6. Project Description

Applicants are required to provide a brief description of the proposed project. Applicants must follow the character limits.

- a. Data Source Will your project use the AQUA Registry Data, the AUA Census Data or both?
- Project Significance/ Background Briefly introduce the project to be addressed. (2,500-character limit)
- c. Project Objective What do you intend to accomplish? (500-character limit)
- d. Project Specific Aims/Approach What overall strategy and methodology will you use to accomplish your aims? (1,500-character limit)
- e. Project Impact Why is this an important problem in urology, and how will your research potentially improve urology practice? (500-character limit)

7. Validate

This section will check for any required information or files missing from the letter of intent.

8. Preview Letter of Intent

Print and preview your letter of intent. Signature of the title page by the applicant/Principal Investigator is not required.

9. Submit

Submit your letter of intent.

B. FULL APPLICATION

After review of the letter of intent, selected applicants will be granted access to the full application submission portal. Much of the full application submission will be populated with information provided in the letter of intent. The application sections are listed below with additional guidance on how to complete each section. Applicants are responsible for ensuring the accuracy and completeness of all materials, and that materials are received in full before the application deadline.

Sections 1-4. Project Title, Download Templates and Instructions, Enable Other Users to Access this Proposal, Applicant/Principal Investigator (PI) Information will be pre-populated from the LOI submission.

1. Project Title

Provide a title for your project (do not use all capital letters)

2. Download Templates and Instructions

The following documents are available for your reference, to assist in completing your application.

- a. 2025 Data Research Program Program Announcement
- b. Instructions for Project Narrative
- c. Biosketch Sample
- d. Biosketch Blank Format Template

e. Data Projects Feasibility Guide

3. Enable Other Users to Access this Proposal

This section enables applicants to give other users access to the letter of intent but is not required.

4. Applicant/Principal Investigator (PI) Information

Applicants will need to toggle between their "Professional Profile" in ProposalCentral and sections of the letter of intent to reference and complete the required information.

- a. AUAID Applicants should enter their AUA member ID.
- b. Name (Last, First, Middle)
- c. Current position or title
- d. Applicant organization
- e. Academic credentials
- f. Contact Information (address, phone, email)

5. Key Personnel (Optional)

Applicants have the option to identify up to 4 co-investigators on the proposed project. All coinvestigators must be current members of the AUA. If you are submitting an application with coinvestigators, please provide the following information for each of them:

Co-investigator

- vii. Name (Last, First, Middle)
- viii. AUA ID
- ix. Current position or title at applicant organization
- x. Applicant Organization
- xi. Academic credentials
- xii. Contact Information (address, phone, email)

6. Upload Attachments Here

Use this section to upload the following application documents, in PDF format.

- a. Applicant biosketch (required)
- b. Project narrative (required) leave out any identifying information such as names, organizations, etc.
- c. References (required) in American Psychological Association (APA) format.
- d. List of abbreviations/ acronyms (optional)
- e. Other relevant documentation (optional)

7. Validate

Click the validate button to check for any missing REQUIRED information or files. Please correct any missing information before proceeding to the next step.

8. Preview Application

Click on the "Print Application" Button to open and print your application. Signature of the title page by the applicant/PI is not required.

9. Submit

Submit your full application.

By submitting an application to the AUA Data Research Program, you agree to the following statement:

By submitting an application to the AUA Data Research Program I certify that the statements and information included in my application package are true and complete to the best of my knowledge. If selected as a participant in the AUA Data Research Program, I agree to all requirements as described in the Program Announcement. I understand that the award will be for a period of up to one year and is contingent on my fulfillment of the reporting requirements.

IV. LETTER OF INTENT AND FULL APPLICATION REVIEW INFORMATION

A. REVIEW AND SELECTION PROCESS

Letters of intent (LOIs) are blind reviewed, and full applications are fully reviewed by a Scientific Review Panel composed of members of the AUA Data Committee. The members are accomplished physicianscientists, who are expert in conducting research using the AUA Annual Census and the AQUA Registry data. Each letter of intent and full application is considered according to established criteria for determining merit as described below.

All review processes are conducted confidentially to maintain the integrity of the selection process. Following the review and deliberation by the Scientific Review Panel, the most highly meritorious applications will be selected to participate in the AUA Data Research Program. Limited feedback will be provided for the letter of intent.

B. LETTER OF INTENT REVIEW CRITERIA

All letters of intent that meet administration requirements will be evaluated for feasibility and will receive an overall impact score, following the NIH scoring guide below:

Overall Impact	Score	Descriptor
	1	Exceptional
High	2	Outstanding
_	3	Excellent
	4	Very Good
Medium	5	Good
	6	Satisfactory
	7	Fair
Low	8	Marginal
	9	Poor

C. FULL APPLICATION REVIEW CRITERIA

All full applications that meet administration requirements will be evaluated against the review criteria below. Each section will receive a score between 1-9 following the NIH scoring guide, and an overall score will be computed. The overall score will be a numerical average of the individual criterion scores,

accounting for weighting of the review criteria as below. Applications from trainees, Early-Stage Investigators (ESI), and providers/researchers from AQUA participating sites will be given special consideration during the application review process. These components from the investigator's credentials and experience may be used as deciding factors between closely rated applications.

Overall Impact and Significance (40%)

- Does the proposed project address a meaningful knowledge gap in urology?
- Does the project have potential to change clinical practice, reduce medical costs and waste, improve patient outcomes, or result in substantial changes in health care policy?
- Does the project address an important problem or barrier to progress?
- How will the field of urology be improved with the results of this project?
- What will the urology community learn from this study?

Innovation (20%)

Is the proposed investigation novel?

Approach (20%)

- Does the applicant describe an overall strategy, methodology, and analyses that are wellreasoned, methodologically valid, and appropriate to accomplish the aims?
- Does the applicant address potential barriers to completion of the study and provide a mitigation strategy to overcome these challenges?
- Does the applicant support the rationale for his/her study with appropriate literature?
- Does the applicant propose to obtain data that sufficiently represents the study population?
- Is the sample size and controls properly justified?

Investigator Credentials and Experience (20%)

- Does the Principal Investigator possess sufficient credentials and a record of successful research projects?
- Is the Principal Investigator an Early Stage Investigator (ESI) or trainee?
- Is the Principal Investigator a provider or researcher from an AQUA participating site?

D. NOTIFICATION OF APPLICATION REVIEW RESULTS

AUA Data Research Program applicants will be notified of funding decisions through ProposalCentral and in writing via email. Reviewer critiques for applications will be accessible via ProposalCentral until December 31st of the application year. To prevent emails from the proposal submission system from being identified as spam, it is strongly recommended to add pcsupport@altum.com to your address book or safe sender list. Please note that results will not be given over the phone.

Applicants selected for participation in the AUA Data Research Program must:

- Provide notice of intention to accept or decline the award offer by email to dataservices@AUAnet.org within 48 hours of receipt of their notification letter.
- Provide verification of current AUA membership in good standing by email to dataservices@auanet.org within one business week of providing an intention to accept notice to the AUA. Please visit http://www.auanet.org/membership for AUA membership information.

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- Submit a high-quality headshot (file size typically ≥1MB) in professional dress or laboratory/white coat via email to dataservices@auanet.org within one business week of providing an intention to accept notice to the AUA. With the submission of this photo, the applicant thus gives consent for its use in AUA publications, advertising, fundraising, or other media activities.
- Additional contracting information will be provided via a Notice of Award within 3 weeks of providing an intention to accept notice to the AUA. Acceptance of the award constitutes agreement to abide by all corresponding Terms and Conditions if the award recipient has not explicitly rejected the agreement in writing to the AUA Data Research Program Administrators within 7 days of receipt of the Notice of Award from the AUA.

V. TERMS AND CONDITIONS OF THE AWARD

GENERAL COMMENTS

For applicants selected for funding, a Notice of Award letter will be issued to notify the grant recipient that an award has been made and to specify the terms and conditions of the award. The Grant Issuing Organization is American Urological Association Education & Research, Inc. Payment of the Grant shall be made in one installment directly to the grant recipient (Principal Investigator) to support the selected research project. If recipient's institution prohibits the recipient from accepting payment directly, the recipient should notify the Issuing Organization Representative immediately to make alternative payment arrangements. Acceptance of this grant constitutes an Agreement between the recipient and the Issuing Organization. Recipient's institution is not a party to this Agreement and this Agreement is not subject to modification by third parties. The Annual Census or AQUA Registry data shall be referred to herein as the "Data".

TEMRS AND CONDITIONS

The AUA Data Research Program award is subject to the requirements set forth in the Terms and Conditions described below. Failure to adhere to the Terms and Conditions may result in revocation of the award, a delay in payment, demand for repayment of any or all Data Research Program funds previously paid to the Recipient or Recipient's assignee, or termination of the award.

In case of disagreement with any Terms or Conditions of this award, the awardee must notify the AUA Data Research Program Administrators within seven (7) days of the date of this Notice of Award in order to resolve the issue(s). The research project referenced shall not commence and the awardee shall not accept any payments until all issues are resolved. The seven (7) day period to accept this award may be extended pending resolution of all issues. If the issues cannot be resolved, this offer of award shall be revoked and the AUA Data Research Program Administrators may, at their sole discretion, select another recipient.

A. REQUIRED MEMBERSHIP(S)

All awardees must be AUA members in good standing for the full duration of the performance period. Proof of membership is required to apply for this Grant and must be provided to the program administrators prior to the project launch and the award payment being disbursed.

B. RESEARCH PROJECT CONTROL

Recipient, as Principal Investigator, is solely responsible for designing and conducting the Research Project, and may designate other investigators under their control ("Investigators"). AUA will have no control or influence over, or involvement in, the conduct of the Research Project. Recipient assumes all applicable regulatory responsibilities for the Research Project, including, but not limited to, obtaining IRB/IEC approvals, regulatory approvals, and any and all reporting obligations to regulatory authorities, as may be necessary by United States law or Recipient's institutional policy. In the event that the Research Project requires submitting an IND or other documents with the FDA, the Recipient will provide to AUA written notice of the intent to file such a submission prior to its filing.

C. REQUIRED REPORTING, PUBLIC ACCESS AND INFORMATION-SHARING

REGISTRATION OF STUDY ON WWW.CLINICALTRIALS.GOV.

If registration of the Research Project or publication of Research Project results on www.clinicaltrials.gov is required by the FDA Amendments Act of 2007 (H.R. 3580) (FDAAA) or other applicable laws or regulations, the Principal Investigator will be responsible for assuring compliance therewith.

All AUA Data Research Program awardees are subject to a public access policy. The AUA reserves the right to include information relating to the grant (such as the Recipient name and project title) in materials issued by or on behalf of the AUA, including periodic reports, newsletters or news releases, the website, or in any other materials issued by or on behalf of the AUA.

In addition, the AUA is a member of the Health Research Alliance (HRA)—a national consortium of nongovernmental, nonprofit funders of biomedical research and training—and has agreed to deposit grant information in the HRA database of privately funded grants, HRA Reporter. The following award information may be provided to the HRA Reporter database and may be shared with the public: investigator name, degrees, clinical specialty if applicable, institution, project title, abstract, grant start date and duration, grant amount and ORCID of the investigator if applicable. HRA aggregates these data for its member organizations and for periodic publication of findings.

D. REPRESENTATIONS AND WARRANTIES

REPRESENTATIONS REGARDING DEBARMENT.

Recipient represents that Recipient: (a) has not been, or is not currently, debarred by the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. §335 (a) or (b) or excluded by the Department of Health and Human Services, Office of Inspector General pursuant to its Exclusion Program and (b) will not employ an Investigator to participate in the conduct of the Research Project who has been debarred by the FDA pursuant to 21 U.S. C. §335. If, during the Term of this Agreement, either Principal Investigator or other Investigators of Recipient involved in the conduct of the Study become debarred by the FDA, Recipient shall notify AUA and perform such other acts consistent with this paragraph.

REPRESENTATIONS OF COMPLIANCE WITH PROFESSIONAL STANDARDS.

Recipient represents that Recipient and other Investigators performing the Research Project will comply with all applicable state and federal laws and regulations, and the standards and practices that are generally accepted, applicable to, and exercised by others engaged in performing similar research, including, as may be applicable, the federal Food, Drug and Cosmetics Act (and specifically including standards of Good Clinical Practices and Good Laboratory Practices), the Anti-Kickback Statute, the PhRMA Code on Interactions with Healthcare Professionals and the AMA Code of Medical Ethics (including, but not limited to, the Guidelines for Gifts to Physicians from Industry).

If Recipient is a member of a Committee, Panel, or similar group ("Committee") that sets formularies or develops clinical guidelines, Recipient agrees to disclose the existence and nature of the relationship described in this Agreement to such Committee and comply with all of the Committee's policies, procedures or rules regarding recusal from decision making.

E. INTELLECTUAL PROPERTY

Recipient warrants that all research and outcomes are the original work of Recipient and other Investigators and do not infringe on the intellectual property rights of any third party. It is recognized and understood that the existing inventions and technologies of the AUA and the Recipient are their separate property, respectively, and are not affected by this Agreement. Neither Party shall have any claims to or rights in such existing Data, inventions and technologies of the other Party. For purposes of this Agreement, "Invention" shall mean any new and useful discovery conceived and reduced to practice, constructively or actually, in the performance of the Research Project, and "Patent Right" shall mean any United States or foreign patent application (including continuations, divisions, and continuations-in-part thereof) that describes and claims an Invention, or any Letters Patent or the equivalent thereof issuing or granting thereon, or reissue, reexamination, or extension thereof. Inventorship shall be determined in accordance with United States patent laws.

F. POLICY ON ARTIFICIAL INTELLIGENCE

Refer to Section I. H. Restrictions to the Use of Artificial Intelligence.

G. AWARD AND REPORTING REQUIREMENTS

All AUA Data Research Program awardees are required to submit outcomes and reporting materials in-full during the performance period. Failure to adhere to the requirements outlined below by the specified deadline(s) may result in a delay of payment of the stipend, or termination of the award.

1. OUTCOMES REQUIREMENTS

By the end of the performance period, awardees must have submitted the following outcomes by email to the AUA Data Research Program administrators at dataservices@auanet.org.

DATA RESEARCH PROGRAM OUTCOMES	DUE DATE
A. Researcher Profile and Lay Language Statement	January 15, 2025
B. Analysis Table Shells	February 28, 2025
C. Mid-Year Progress Report	June 30, 2025
D. Abstract for AUA News	August 1, 2025 – December 31, 2025

E. Abstract for submission to scientific meetings	August 1, 2025 – December 31, 2025
F. Draft Manuscript for submission to peer-reviewed journals	August 1, 2025 – December 31, 2025
G. End of Year Progress Report	December 31, 2025

Awardees are encouraged to attend the AUA Annual Meeting or other scientific meetings to present their research supported by the AUA Data Research Program. Additionally, awardees may be invited by the AUA or its affiliates to participate in interviews, videos, podcasts, panels, etc., to serve as subject matter experts or in support of promotional activities for the Data Research Program.

2. PROFILE AND LAY LANGUAGE STATEMENT

Data Research Program awardees (principal investigators) will be highlighted in the AUA's Member Monday and other features on social media platforms. Awardees will be required to submit a short profile ahead of their scheduled feature.

All awardees must submit a 5-6 sentence lay-language statement about their research projects to be posted under current AUA-supported research at www.auanet.org, in press releases, and other promotional materials for the AUA Data Research Program. Statements will be due no later than January 15, 2025, and should be submitted via e-mail to dataservices@auanet.org. This information will only be used for the promotional purposes described above.

3. RESEARCH PROJECT DESIGN, ANALYSIS, AND DELIVERABLES

Awardees are required to actively participate in the project design phase, review of the research methodology employed, and validation of the results. Awardees should submit comprehensive data analysis table shells by February 28, 2025, that will serve in establishing the analysis plan and the scope of the project. AUA statisticians may request that awardees prioritize or scope their analyses during the project design phase to ensure completion of one manuscript within the DRP project timeframe and allotted project resources.

AUA statisticians will provide results based on the table shells provided, and awardees are allowed at most two rounds of revisions to the analysis. Once final results are validated, awardees are responsible for developing abstracts, manuscripts, posters, presentations, etc. for dissemination.

4. AWARDEE PROGRESS REPORTS

By **June 30, 2025**, awardees must submit a mid-year progress report. The report must be submitted to the Program administrators and the AUA Data Committee by e-mail (dataservices@auanet.org). A final progress report is due by December 31, 2025. Reports should be approximately two pages and include the following information as applicable, based on the stage of the project:

Section One – Identifying Information

Award Recipient:

Project Title:

Institution:

Co-Investigators:

Performance Period:

Date Submitted:

Section Two – Award Progress & Outcomes

- A. Summarize the main focus of the research.
- B. Clearly state the findings.
- C. Specify how the research results met (or did not meet) the objectives established in the proposal.
- D. Provide a description of any challenges or issues that impeded progress of this project.

Section Three – Award Products (include in mid-year and end-of-year progress reports, as applicable)

List any of the following achieved during your performance period. If none of the below were achieved during your reporting period, simply state "Nothing to report."

- A. Publications (peer-reviewed) in scientific, technical, or professional journals
- B. Publications in other platforms (e.g.: AUANews)
- C. Abstracts and Presentations
- D. Websites or Other Internet Sites
- E. Technologies or techniques established
- F. Other products (if applicable)

Section Four – Impact on Urology Research & Practice (include only in end-of-year progress report)

State what the impact or potential impact of the results of the project are in the research literature, on the practice of urology, and for urology patients. Describe how findings, results, and/or techniques that were developed or other products may make an impact on the base of knowledge in urology. Summarize using language for the lay audience.

Section Five – Personal Statement (include only in end-of-year progress report)

Include a personal statement from the awardee on their experience during the award period.

5. ADDITIONAL OUTCOMES REPORTING

Following the completion of the performance period, the AUA Data Research Program administrators may contact previous awardees to collect additional award outcomes information including, but not limited to, publications, funding, invited speakerships and presentations, and leadership positions within the AUA or affiliated organizations. The AUA request that all past awardees provide updated contact information when appropriate and be responsive to requests for post-award information.

H. RIGHT OF FIRST REFUSAL TO PUBLISH

AUA shall have the right of first refusal to publish any works created by or derived from the Data provided hereunder.

I. ACKNOWLEDGEMENT REQUIREMENTS

Awardees are required to send electronic copies of articles published based on AUA Data Research Program funded-research to the Program administrators and the AUA Data Committee at <u>dataservices@auanet.org</u>. Any abstract, publication, poster or presentation arising from work supported in whole or in part by this program must include the following acknowledgment:

"This work was supported in part or in full by the American Urological Association Data Research Program."

J. FUNDING REQUIREMENTS

1. STIPEND DISBURSEMENT

The AUA Data Research Program stipend will be paid directly to the Principal Investigator via wire transfer in one installment in July 2025, contingent upon receipt of the mid-year progress report. Awardees are responsible for providing the AUA Data Research Program administrators with finance information as needed to coordinate payment. Awardees must submit their financial information to the AUA by **February 15, 2025.**

For Domestic Recipients:

Complete the IRS W-9 Form - W-9 Form (Secure Link).

For International Recipients:

- Complete the IRS W-8BEN Form W-8BEN (Secure Link).
- Complete the Wire Transfer Information Request Form Wire Transfer-Bank Info (Secure Link).

The AUA does not withhold taxes from stipends (federal withholding, social security, local or state taxes, etc.). Taxes and other withholdings are the responsibility of the awardee.

Refer to Section I. F. Allowable Use of Stipend for more information.

K. INSTITUTIONAL REVIEW BOARD (IRB)

IRB letters of approval are **NOT** required from participants, as all research supported by the AUA Data Research Program will be based on AUA data with existing IRB approvals.

VI. CHANGES TO APPLICANT INFORMATION OR RESEARCH PROJECT

Changes Post-Application Submission

Any changes impacting the Research Project (i.e., applicant contact information, project information, key personnel, etc.) that occur after the proposal submission deadline MUST be reported to the AUA Data Research Program administrators via email at dataservices@auanet.org. All changes will be reviewed to determine whether the submitted proposal may continue to the Scientific Review Panel review or must be withdrawn.

Award Modifications Requirements

Any changes in the Research Project (e.g., scope, objectives, duration), key personnel, level of effort, institution, or contact information that occur after the proposal is selected for funding or during the award performance period must be reported in advance to and approved by the AUA Data Research Program administrators and/or the AUA Data Committee .

VII. CONTACT INFORMATION

The Issuing Organization Representative is responsible for the negotiation (if applicable) and administration of this award and for interpretation of award administration policies and provisions. This representative is also responsible for oversight of the programmatic and technical aspects of this project.

Questions or requests related to the AUA Data Research Program Announcement, submission requirements, or the award should be directed to the AUA Data Research Program administrators. The preferred method of communication is by email to dataservices@auanet.org. Assistance is typically available Monday through Friday from 9:00 a.m. to 5:00 p.m. EST. Please allow two business days for response time.