INNOVATION IN REGULATORY SCIENCE AWARDS (IRSA)

Request for Proposals:
February 11, 2027 by 3:00 pm (EST)

BURROUGHS WELLCOME FUND

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KEY DATES

Grant application portal available	On or before October 15, 2026
Proposal application due	February 11, 2027, 3:00 pm (EST)
Invitation for finalist interview *(or notice of declination)*	April 27, 2027
Finalist interviews	June 9, 2027
Notice of award	By August 1, 2027
Award start date	September 1, 2027
New Awardees Convening	TBD, September/October, 2027
Award end date	August 31, 2032

PROGRAM BACKGROUND

The Burroughs Wellcome Fund (BWF) recognizes Regulatory Science as an important yet underfunded area of research. Through this initiative, BWF aims to stimulate innovation in this area and strengthen the evidence needed to support regulatory decision-making.

Regulatory science includes the development and evaluation of new tools, standards, and approaches used to assess the safety, efficacy, quality, and performance of products and interventions that affect human health. Regulatory science has become an increasingly important component of fostering innovation while maintaining public trust and protecting patients/consumers/the public.

As biomedical science and technology continue to evolve at a rapid pace, the process of translating discoveries into products/interventions has become increasingly complex. Regulatory science must advance alongside these scientific developments to ensure that new approaches can be evaluated rigorously, efficiently, and appropriately. For example, preclinical animal models of human disease are often poor predictors of human outcomes, which has led to the rise of new approach methodologies in drug development, thus creating a need for innovative ways to evaluate such methodologies to justify their use in regulatory decision-making.

Similarly, advances in precision medicine have highlighted the need for biomarkers that can reliably predict which individuals are most likely to benefit from a therapeutic intervention, experience adverse effects, or require alternative treatment strategies. This need is particularly evident in areas such as mental health, where patients with the same diagnosis may respond very differently to the same treatment and where objective biomarkers remain limited. Developing and validating biomarkers that better characterize disease, predict response, or identify meaningful patient subgroups could improve clinical trial design, strengthen evidence generation, and support more informed regulatory decision-making.

BWF is particularly interested in regulatory science approaches that responsibly improve or accelerate the development, evaluation, or implementation of products and interventions affecting human health while preserving scientific rigor, quality, and safety. In many cases, important regulatory questions arise because therapeutics, devices, diagnostics, etc., may perform differently due to interindividual variation in biological, environmental, behavioral, social, and other factors. Improving understanding of these sources of variation can strengthen evidence generation, inform regulatory decision-making, and help ensure that products and interventions are safe and effective for those who ultimately use them.

For the purposes of this program, we seek regulatory science proposals that develop tools, standards and approaches that have the net effect of responsibly accelerating and/or improving the development of regulated products and interventions. When relevant, projects should seek to determine the biological and nonbiological variables that underlie interindividual variability associated with the use of or response to regulated products/interventions. Regulatory science questions should address important unmet needs in areas including but not limited to: biomarker development and qualification, endpoint development, regenerative medicine (including gene therapy), artificial intelligence and

machine learning, digital health, reduction of animal testing and new approach methodologies, model-informed product development, regulatory approaches that accelerate drug repurposing, and approaches that empower patients and consumers. While we anticipate that many projects may relate to therapeutics or medical devices, the program is not limited to these areas, nor is it limited to a particular regulatory authority.

Innovation in Regulatory Science Awards Overview

BWF's Innovation in Regulatory Science Awards provides $500,000 over five years to academic researchers developing innovative tools, standards, and approaches in regulatory science that will ultimately inform regulatory decisions made by the FDA, Health Canada, and/or other regulatory or standards-setting bodies responsible for protecting human health and safety. Responsive projects may address regulatory questions involving traditional therapeutics, biologics, and devices; BWF will also consider projects involving diagnostics, food, consumer products, or other areas affecting human health and safety, provided that the work develops an innovative approach to address a clearly defined and important regulatory science problem, and a strong case is made regarding its potential to significantly impact human health.

This funding mechanism is NOT intended to fund the development of therapeutics/biologics/interventions themselves. Therefore, applicants should not propose development of a new drug or device as the primary goal of the project, as this is out of scope. The primary goal should be to develop a regulatory science innovation (tool, standard, approach, etc.) that informs regulatory decision-making.

Special Considerations

- Proposals that seek to improve or responsibly accelerate development of products and interventions while preserving scientific rigor, quality, and safety are especially encouraged. Projects should account for interindividual variation associated with the use of or response to regulated products and interventions.
- BWF strongly encourages applications from persons who have been historically underrepresented in the research enterprise, including but not limited to: women of any ethnic or racial group; any person identifying as Black or African American, Latino/a or Hispanic American, Native American, Alaska Native, Native Hawaiian, indigenous to the Pacific Islands, indigenous Canadian; persons with disabilities; persons from disadvantaged backgrounds; and individuals who identify as LGBTQIA+.
- In addition to seeking participants from the historically underrepresented groups described above, BWF is also interested in increasing diversity based on characteristics such as geographical location of institution, personal experiences and background. If desired, lived experiences based on any of the characteristics mentioned in these first two bullets may be addressed in the personal statement for consideration.
- BWF believes that a diverse scientific workforce is essential to the process and advancement of research innovation, academic discovery and public service. This belief is grounded in a wealth of evidence demonstrating time and again that diverse teams outperform homogeneous ones.

ELIGIBILITY REQUIREMENTS

To understand the expectations of the Innovations in Regulatory Science Awards (IRSA) program, it is important to read the eligibility requirements below, in addition to the proposal elements, terms of grant, and selection. The FAQs may also provide eligibility clarification.

Degree/Role Requirements

- Candidates must hold an M.D., Ph.D., D.V.M., D.D.S., D.O., D.Phil., Pharm.D., or M.D.-Ph.D. degree.
- Candidates must hold a faculty position, tenure-track or non-tenure track, or adjunct faculty position at a non-profit institution in the United States or Canada; grants are made to the institutions on behalf of the Primary Investigator.
- Candidates must be an investigator at the adjunct, assistant, associate, or full professor level.
- Primary Investigators are required to devote no less than 50% of their time to research-related activities. This requirement refers to the Primary Investigator's overall research portfolio and does not require that 50% effort be dedicated to the proposed IRSA project alone. Research effort supported by other grants, institutional funding, or research activities may count toward this requirement.
- Postdocs are not eligible.

Institutional Requirements

- Grants can only be made to non-profit institutions [501(c)(3) or equivalent] in the U.S. or Canada on behalf of the Primary Investigator.
- Candidates must be based at public or private nonprofit organizations [501(c)(3) or equivalent] in the United States or Canada, including degree-granting academic institutions, research institutes, and teaching hospitals affiliated with academic degree-granting institutions. A 501(c)(3) organization is an American tax exempt, nonprofit organization. Candidates should check with their institutional officials to confirm the institution's classification.

Citizenship/Residency Status

- Citizens and non-citizen permanent and temporary residents of the U.S. and Canada who are legally qualified to work in the U.S. or Canada are eligible. Candidates who are temporary U.S. residents must hold a valid U.S. visa (J-1, H1B, F-1 or O-1 visas). Temporary Canadian residents must hold a valid Canadian visa (Study Permit, C-43, C-44, C-10, or C-20 work permits/visas). If a grant is awarded and the candidate's visa does not allow for such a stay, BWF may terminate the grant. BWF will not intercede on behalf of non-citizens whose stay in the U.S. may be limited due to their visa status. Your institution must verify your immigration status as part of your application.

General Requirements

- Candidates may self-nominate but need to obtain approval by an official for sponsored programs at the institution where the work will be performed.
- Applications must be submitted by the Primary Investigator (PI). The PI may have up to a total of two co-investigators. Co-investigators do not need to be at the same institution; however, the person submitting the application must be designated as the primary investigator and must meet all eligibility requirements.
- Candidates may not submit more than one IRSA application per award cycle.
- Candidates may re-apply in subsequent years as long as they remain eligible.
- Candidates must agree to the Terms of Grant.
- Candidates who currently hold a competitive BWF award are not eligible to receive an IRSA award. If a current BWF competitive award recipient/Primary Investigator applies for and is selected for an IRSA award, they must choose between accepting the IRSA award and relinquishing their existing BWF award or declining the IRSA award and retaining their current award.

IMPORTANT NOTE

Candidates with questions about their eligibility must contact BWF in advance of the application deadline. BWF will make no exceptions to its policies.

HELPFUL LINKS AND POINTS OF CONTACT

Please review our online Frequently Asked Questions first. Information about Burroughs Wellcome Fund and the Innovation in Regulatory Science Awards can be found on our website and at the links below.

- 2023 Innovation in Regulatory Science Awards – Discussion with Past IRSA Awardees Webinar A recording of Dr. Tammy Collins, Program Officer and a panel of three IRSA Awardees presenting an overview of the IRSA grant award, the awardee experiences in responding to the RFP solicitation, and the impact the award has had in supporting their research.
- IRSA Advisory (Review) Committee Members.
- Past IRSA Grant Recipients.

For eligibility and programmatic questions related to the Innovation in Regulatory Science Awards, please contact BWF program staff at irsa@bwfund.org.

Technical questions regarding use of the ProposalCentral system should be directed to:

ProposalCentral Support
1-800-875-2562 (8:30am to 5:00 pm ET M-F, except holidays)
pcsupport@altum.com

SELECTION PROCESS

The Innovation in Regulatory Advisory Committee will review all proposals, interview finalists, and make recommendations for awards to the BWF Board of Directors.

Competitive applications will clearly define realistic, actionable and measurable approaches to advance regulatory science research. Proposals will be evaluated based on the following categories:

Significant and Equitable:

- Addresses an important regulatory problem or critical barrier to product development.
- Advances regulatory science approaches that account for/determine the causes of biological and nonbiological interindividual variation in response to/use of products/interventions when relevant to the scientific or regulatory question.
- Utilizes minority health and health disparities research best practices.

Implementable:

- Presents a clear, timely and implementable strategy or solution to a regulatory problem.
- Presents a research strategy that is well-reasoned, organized and appropriate.
- Identifies appropriate collaborators (e.g., regulatory officials, community-based organizations, standards organizations, etc.) that can facilitate the feasibility, validation, dissemination, and/or adoption of project findings.
- Addresses whether the approach has demographic limitations and describes actions to define and/or address these limitations.

Innovative and Impactful:

- Describes a creative and original approach.
- Has a high likelihood of benefitting society and improving/preserving human health.

Investigator Leadership and Impact:

- Has experience with and a general understanding of regulatory science.
- Demonstrates a strong publication history.
- Demonstrates respectability within their field by providing positive reference letters and personal statements.
- Has a history of cultivating collaborative and collegial relationships.
- Provides an impactful and unique voice to the IRSA community based on characteristics such as institution, personal experiences, gender, race/ethnicity.

Selected finalists will have the opportunity to present their research during interviews with the advisory committee. The applicant submitting as the primary investigator is required to participate in the interview. Co-investigators cannot interview on behalf of the applicant, or join the interview discussion.

Candidates selected to participate in finalist interviews will be notified by April 27, 2027. The finalist interviews are scheduled to be held on June 9, 2027.

BWF does not provide critiques of unfunded proposals.

TERMS OF GRANT USE/USE OF FUNDS

The following summarizes select grant terms and conditions that may apply to awards made through this program. This summary is provided for informational purposes only and is not intended to be a complete statement of all award requirements. Successful applicants will receive a grant agreement for execution that sets forth the full terms and conditions of the award.

Use of Funds

BWF's Innovation in Regulatory Science Awards provide up to $500,000 over five years to academic investigators who are addressing research questions that will lead to innovation in regulatory science with the potential to improve regulatory processes and responsibly accelerate and/or improve the development of products/interventions affecting human health, without compromising scientific rigor, quality, or safety and with appropriate consideration of interindividual variability.

Budget Submission

BWF utilizes ProposalCentral to manage grant awards including budgets and expenditures. Submission of a grant proposal will require submission of an itemized budget and budget justification for each period of the grant award, in accordance with the budget allowances and limitations outlined in this RFP and Terms & Conditions. All budget narratives must show calculations for all budget items and must clearly justify/explain the need for these items. ProposalCentral's high-level budget categories include Personnel, Equipment, Supplies/Materials, Meetings/Travel/Professional Development, Participant Support Costs/Program Costs, Consultants, Evaluation, and Other.

Projected Annual Funding Levels:

The following is a breakdown of the funding levels of support provided during each year of the grant award:

- Year 1: $100,000
- Year 2: $100,000
- Year 3: $100,000
- Year 4: $100,000
- Year 5: $100,000

The award term normally will be five years. Awardees demonstrating adequate progress may be granted no-cost extensions up to five additional years, not exceeding 10-years from the award start date. For example, for awards issued on September 1, 2027, awardees may request no-cost extensions for up to two-year intervals to extend awards through no later than August 31, 2037.

The following stipulations apply for use of BWF IRSA funds:

Salary and Fringe Benefits

- **Awardee/Primary Investigator Salary & Fringe:** A maximum of $30,000 of grant funds may be used annually towards the award recipient's/Primary Investigator's salary and fringe benefits. If grant funds are applied towards fringe benefits, no more than $10,000 per year of the $30,000 salary and benefit limit may be applied towards fringe benefits.
- **Co-Investigator Salary & Fringe:** A maximum of $30,000 per year per person may be allocated for the salary and fringe benefits of up to two Co-Investigators (Co-PIs). If grant funds are applied towards fringe benefits, no more than $10,000 per year of the $30,000 salary and fringe benefit limit may be applied towards fringe benefits.
- Across this leadership team (one PI and up to two Co-PIs), the combined maximum may not exceed $90,000 per year in total salary and fringe benefit support. Any Co-PI receiving funds must be clearly identified in the grant application. If a Co-PI is proposed after the award is made, prior approval from the Program Team is required before allocating funds.

Additionally, the following personnel stipulations apply:

- These limits on salary and fringe benefits do NOT apply to salary and fringe benefits for personnel working within the Primary Investigator's lab.
- It is expected that the institution will supplement the Primary Investigator's salary and fringe benefits. Should extraordinary circumstances warrant a need to use more of the grant funds for salary and fringe benefits to support the Primary Investigator, prior approval MUST be obtained from the BWF Program Officer.
- BWF does not set or cap the salary level of its award recipients (Primary Investigator), nor does it require a minimum amount of the grant to be used to cover salary.
- Any remainder of the grant funds not used to support the salary and fringe benefits shall be used for expenses relating to the Primary Investigator's research.

- If, during the grant period, the Primary Investigator assumes an administrative position within his/her Institution (e.g., division chief, department chair), the Institution and the Primary Investigator shall promptly notify BWF. BWF will determine if the Primary Investigator can reasonably meet the terms of the Grant. The expectations for research productivity will not change for awardees who accept an administrative position. Written materials beyond the progress report, documenting research activity, may be required of the Primary Investigator.

Allowance for Research Expenses

- The support allocated for research is under the control of the Primary Investigator and may be used flexibly for items to include but not limited to: consumable supplies, equipment, personnel, and travel to scientific meetings or between members of research groups, sample acquisition for studies, collection of pilot and other data, and resources to support protocol generation. Also, analysis costs, animal studies, or human subject recruitment can be supported by this Grant. The use of research expenses is at the reasonable discretion of the Primary Investigator to execute the goals set forth in the Proposal.
- Prior written approval by BWF is required within any one fiscal year when equipment purchases exceed $50,000, travel costs exceed $15,000, or research goals and objectives change substantially from the proposal.

Indirect Costs

- Indirect costs may not be charged against the grants. Please refer to BWF's Direct and Indirect Costs Policy for guidance on how BWF classifies direct and indirect costs.

Tuition and Fees

- No BWF Grant funds may be used towards tuition and fees.

Supplemental Funds

- Award recipients may obtain funds from other sources for research in the same or similar areas as that conducted under these grants, so long as there is no conflict with meeting the terms of BWF's award. The Primary Investigator may not hold concurrent competitive BWF awards.

Carryover, No Cost-Extension and Return of Unspent Funds

During the award period, unused research funds may be carried over to the succeeding year. At the termination of the grant period, unspent grant funds that exceed 5% of the original grant awarded or $1,000 (whichever is less) must be returned to BWF within 30 days, unless the Primary Investigator transfers to a new institution. The Primary Investigator may receive a no-cost extension for 12-24 months; requests explaining why an extension is needed must be submitted in writing within Proposal Central prior to the end of the award.

Post-Award Management

Grants are made to institutions on behalf of the Primary Investigator. The institutions must qualify as a 501(c) (3) or equivalent and the institution's most current U.S. Tax Determination Letter must be on file with the Burroughs Wellcome Fund (BWF). The institutions are responsible for disbursing the funds and for maintaining adequate supporting records and receipts of expenditures.

Payments

IRSA awardees receive a total award of $500,000 over five years, with payments generally issued in semiannual installments of $50,000, contingent upon satisfactory progress, completion of required reporting and compliance activities, and maintenance of an appropriate award balance through the expenditure of funds paid.

Award Transfers

Awards may be transferred to another non-profit Institution in the U.S. or Canada, only with the written approval of BWF. The award will be terminated for awardees transferring to Institutions outside of the U.S. or Canada; the balance of any unused award funds shall be returned to BWF.

To initiate the transfer process, the grantee must submit a written request explaining why the transfer is needed at least three months prior to the proposed transfer date.

Award recipients who change institutions may take with them any equipment or supplies purchased under the award. The balance of any unused award funds shall be returned to BWF and BWF will transfer these funds to the new institution.

The new institution must enter into a new written agreement with BWF before the funds will be transferred to the new institution.

Progress and Financial Reporting

The Primary Investigator must provide BWF with an annual progress report, and institutions must submit an annual expenditure report from the financial officer of the institution according to the dates specified in the grant agreement. The reports must be submitted in the format provided by BWF, the current format is available through BWF's grants management system, ProposalCentral. Continued funding will depend on both the timely submission of these reports and their favorable review by BWF and its program advisory committee.

Publications, Intellectual Property and Dissemination of Findings

Scientific publications or presentations that result from these awards must acknowledge the Primary Investigator's receipt of a Burroughs Wellcome Fund Innovation in Regulatory Science Award. Copies of journal articles and other publications should be sent to BWF along with the annual progress report.

Primary Investigators should follow their institutions' patent, copyright, and licensure policies for discoveries resulting from research carried out under this grant and for which a patent, copyrights, or licenses are sought. BWF will not retain any rights to patents, copyrights, or intellectual property that result from research carried out under this grant and will not retain any rights to publish the results of the funded research.

The Primary Investigator should share research supported by this grant through recognized means, e.g., publications and/or presentations of results in scientific forums. BWF encourages, but does not require, awardees to publish in open access journals and pre-print for peer feedback.

Compliance

The awarded institution should, and should require the Primary Investigator to, comply with all applicable institutional policies and local, state, and federal laws and regulations, including, but not limited to, the policies and regulations governing radioactive substances, recombinant DNA, toxic materials, specific environmental regulations, conflict of interest, conflict of commitment, code or standard of ethics, financial matters and reimbursements, or any applicable policy of the awarded institution. Additionally, the institution and Primary Investigator should require any postdoctoral fellows, graduate and undergraduate students supported by this grant, and other study personnel to also comply with these requirements. BWF expects that appropriate federal, state, and local guidelines with regard to scientific misconduct are in place and enforced at all institutions with which BWF award recipients are affiliated.

If any aspect of the funded research involves the use of human subjects, approval of the institution's review board/committee on human research must be obtained prior to grant initiation. Such research must also comply with appropriate federal, state, and local regulations pertaining to the use of human subjects in research.

If animals are to be used in research, the animal facilities and the care of the animals must conform to the regulations of appropriate federal, state, and local regulations pertaining to the use of animals in research. Approval by the institution's review board/committee on animal research and care, or equivalent institutional body must be obtained prior to grant initiation.

APPLICATION INSTRUCTIONS AND SUBMISSION GUIDELINES

Overview of Application Process

Applying for this award is a two-stage process.

1. **Proposals.** The grant application portal will be available by October 15, 2026. Interested candidates who meet the eligibility criteria may submit one online proposal through ProposalCentral by **February 11, 2027 (3:00 pm EST)**. Instructions on how to prepare a full research proposal are provided on page 10. In brief, the application includes applicant information (to be completed within the grant portal), proposal elements (with components to be completed within the grant portal or uploaded as a PDF), plus the letters of recommendation to be uploaded confidentially by each recommender.
2. **Interviews.** Participation in an interview will be by *invitation only* after review of full application proposals. A selected group of applicants will be invited to participate in an approximately 20-minute interview with the IRSA Advisory Committee and BWF staff, conducted virtually over Zoom. We will reach out by the end of April 2027 to invite finalists for interviews and to coordinate the scheduling process.

Registering on ProposalCentral

ProposalCentral is an application and grants management system utilized by multiple funders. Applicants may already have an account on the site.

If the applicant/candidate does not have an account, the candidate must register on ProposalCentral by clicking the "Need an account?" button and creating a professional profile, including a unique user ID and password. Remember the login and password to access the application later. Applications do not need to be completed in one sitting.

If a professional profile has already been created, the candidate must verify the information for accuracy before submitting a completed application. Demographic data in the professional profile is for statistical use only.

When creating the professional profile, candidates will be asked to add a primary institution. This is the institution where the applicant currently holds a position. It is likely that the institution already has a profile on the system. To search for the institution:

- Input the institution name (partial) and click display results.
- Information from the institutional profile will automatically populate, including the institutional officer.
- If your institution is not listed on ProposalCentral, please reach out to the ProposalCentral technical support staff to help with this process.

Candidates have the option of linking their ORCID iD to their ProposalCentral account. ORCID iD is a persistent digital identifier that is unique to individual researchers, where one can keep their CV information current and share with other systems. BWF does not require the use of ORCID iD at this time, but it is highly suggested. Visit the ORCID website for additional details. To start a LOI from the professional profile, locate the red "Create New Proposal" button.

Preparing Your Full Proposal Application

Proposals must be submitted through ProposalCentral, by February 11, 2027, at 3:00 p.m. (EST).

Overview of Proposal Application Elements

To be completed in web forms:

1. Title/General Proposal Information
2. Applicant Information
3. Applicant Demographics
4. Nominating Institution & Contacts
5. Recommender & Co-Investigator Contacts
6. Request Recommendation Letter
7. Lay abstract (limit of 3,000 characters, including spaces)
8. Scientific abstract (limit of 3,000 characters, including spaces)
9. Budget Detail & Summary
10. Organizational/Proposal Assurances for Human Subjects
11. Listing of three peer-reviewed scientific publications/ manuscripts
12. Personal Statement from primary applicant (limit of 4,500 characters, including spaces)
13. Implementation Plan (limit of 4,500 characters, including spaces)
14. Facilities and Resources Summary (limit of 5,500 characters, including spaces)
15. Applicant/PI Signature (required, prior to deadline)
16. Institutional Signing Official Signature (required, prior to deadline)
17. Co-Investigator(s) Signature (only required if co-investigators are proposed, prior to deadline)

To upload to the application as a PDF:

18. NIH Biosketch* (for primary applicant and each co-investigator, 5-page limit for each)
19. Organizational/Proposal Assurances IRB Certification (one-page limit, if applicable)
20. Research Plan (6-page limit, not including Bibliography)
21. Bibliography (optional, 4-page limit)
22. Copies of Peer-Reviewed Scientific Publications/ Manuscripts (three required)
23. Recommendation Letters – confidential (two required)

Helpful Tips for Planning Ahead

- A complete application must be submitted through the online application system by 3:00 p.m. EST on February 11, 2027. The system will automatically close at the deadline, and applications or revisions submitted after that time will not be accepted.
- All communications, including invitations to participate in finalist interviews and declinations, will be made through email and the grantee portal, ProposalCentral.
- For some individuals, the autogenerated emails from ProposalCentral may be delivered to a junk/spam folder. It is recommended that candidates contact their referees, co-investigators, and signing officials, to ensure these individuals receive and respond to the email notifications and complete required tasks in ProposalCentral before the noted deadlines.
- A proposal application will require a signature from the Primary Investigator, up to two-Co-Investigators (if proposed), and the institution's authorized Signing Official prior to submission. Many institutions require internal review and approval before grant applications requiring institutional signatures can be submitted. Your institution may require you to complete additional forms or documentation for internal review beyond the requirements of this application. Lead times for obtaining approval may range from a few days to several weeks. Applicants are strongly encouraged to contact their grants or sponsored research office early to confirm internal procedures and deadlines for institutional sign-off for grant submissions.
- All attachments must be uploaded as Portable Document Format (PDF) files. All documents must have a minimum 11-point font with one-inch margin.
- NO EXCEPTIONS OR EXTENSIONS WILL BE GRANTED. After the deadline, applicants with incomplete proposals and those not adhering to instructions will be disqualified. Only proposals and recommendation letters submitted through the BWF online application website will be accepted.

The following instructions will provide additional guidance on the requirements for the BWF IRSA application and how to submit the proposal through ProposalCentral.

*The RFP requests submission of an NIH-style biosketch for PIs and co-investigators. Please note that we do not require that it be made and certified in SciENcv. You have the flexibility to craft an NIH-style biosketch in a manner that is most convenient to you, utilizing past NIH templates for your submission.

Creating a New Proposal

To begin an application from the Home Tab in ProposalCentral:

- Locate the Home tab within ProposalCentral and click the red "Create New Proposal" button.
- Use the "Filter by Grantmaker" button to select the Burroughs Wellcome Fund.
- Locate Innovation in Regulatory Science Awards and click the "Apply Now" button.
- Verify that an application is being created for the Program: Innovation in Regulatory Science Awards, enter the project title and hit "Save."
- Complete the application now or save and revisit later.

Completing Proposal Elements

The following is a summary of the proposal elements as they appear in the ProposalCentral system and instructions for completing them. The proposal elements must be complete prior to submission. Most elements will be entered into ProposalCentral's webform fields, some will be uploaded in PDF format by the applicant or confidentially by referees. All fields with a red asterisk in the system are required.

Title Page

Enter the project title to begin the application (limited to 150 characters with spaces). Click "Save" to be able to return to the proposal at a later time. Answer additional questions on the page, indicating how you heard about the program and if you are a former applicant or awardee.

Download Instructions

In this section, candidates can download a copy of this IRSA RFP document which includes instructions for completing this application.

Enable Other Users to Access this Proposal

This section allows applicants to grant access to others that need access to the proposal (e.g., other individuals assisting you in preparing, editing, or submitting the proposal). A candidate may grant three levels of access: View only, Edit (cannot submit), and Administrator (edit and submit). Only registered ProposalCentral users can be given access to the system. Individuals can register for a ProposalCentral user account at this link. To search for a user with an existing account, enter their User ID/email address in the space provided and click "Find User."

Signing Officials will automatically be given access to the application. If the primary applicant would like to give access to co-investigators, they may do so here.

Applicant Information

In this section, information is pre-populated with information from your professional profile. The following information **must** be completed in the professional profile (and it will populate in the Applicant/PI section). **Applications with incomplete professional profile sections will be rejected out of fairness to all applicants.** To edit this information, click the "Edit Professional Profile" button:

- **PI Institution and Address:** Provide the name of the PI institution, along with the division and department. The PI institution is the institution where the primary applicant currently holds a position and intends to conduct their research. If you need to change the institution, within the "Edit Professional Profile" window, click the "Change Institution" button to select a new institution. It is likely that your institution already has a profile in ProposalCentral and can be added through a simple search. If your institution does not have a profile with ProposalCentral and/or if any institutional information is incorrect, please reach out to the ProposalCentral technical support staff and your institutional representatives to help with this process.

  In this section you will also include the PI's institution/professional Address, City, State, Zip, Country; PI contact information including email address, work, and mobile phone numbers.
- **PI Employment Information:** Provide the Academic Rank and Primary Job Function for the PI.
- **Highest Degree(s):** Enter information for your highest degree (e.g., doctoral degree) to include the degree type (e.g., Ph.D.) and the date you received your degree by the conferring institution.
- **Baccalaureate/Post-Baccalaureate Degree(s) Table:** Enter your degree information in the fields provided. See, "Edit Professional Profile", section 2 "Degrees" to complete or update the table, providing the degree type, year awarded, and awarding institution for each degree awarded including bachelors, masters, and doctoral degrees.

  After completing these edits to your professional profile, click save, and click "Return to LOI/ Proposal" to continue working on the next section of the Proposal application.
- **PI Institution Type:** Indicate whether or not the nominating institution for which you're applying on behalf of is a degree-granting institution. Note, both degree-granting and non-degree granting institutions are eligible to apply for this award. This data is collected for statistical use only.

In addition, upload the following at the bottom of the page:

- **Biosketch:** Upload a current NIH-style Biosketch

  The RFP requests submission of a PDF of an NIH-style biosketch for PIs and co-investigators. Please note that we do not require that it be made and certified in SciENcv. You have the flexibility to craft an NIH-style biosketch in a manner that is most convenient to you, utilizing past NIH templates for your submission.

Applicant Demographics

In this section, the applicant will respond to questions to provide details about their gender, race, ethnicity, disability status, citizenship, and residency status. The information collected in this section is confidential. This data is for statistical use only.

Nominating Institution and Administrative Contacts

The nominating institution is where the proposed work will be performed, is the institution where the primary investigator holds an appointment, and the institution that will receive and administer the grant.

Provide information for the nominating institution, including the institution name, address, contact information, and IRS EIN/TIN. This information may auto-populate from your professional profile. To revise your nominating institution, click "Change Institution." If any information is incorrect, contact ProposalCentral Technical Assistance and the institution contacts listed to update the institution profile.

Candidates MUST apply from a non-profit organization [501(c)(3) or equivalent] in the U.S. or Canada. These organizations may include degree-granting academic institutions, research institutions, and teaching hospitals affiliated with academic degree-granting institutions. A 501(c)(3) organization is an American tax exempt, nonprofit organization. Candidates should check with their organization's officials to confirm their tax classification.

Applicants often select institution profiles associated with their department, lab, or division rather than the legal entity submitting the application. If you are applying on behalf of a university, hospital system, research institute, or other organization, verify with your grants or sponsored programs office the correct legal institution name and ProposalCentral profile to use before submitting your application.

- **Signing Official & Financial Officer Contact Information:** Applications will need to be approved by an official responsible for sponsored programs (generally from the institution's grants and contract's office, office of research, or sponsored program's office). The Signing Official and Financial Officer should be added in this section. An autogenerated email will be sent to the Signing Official and Finance Officer notifying them that an application is in progress.

  Later in the application in the section "Institutional Certification & Required E-Signatures" the Signing Official for your institution will need to certify that: 1) you are eligible for the award, 2) that the institution approves the application submission, and 3) that the institution is eligible to receive the award. While the application does not require a signature from the Financial Officer, the Financial Office is responsible for completing the financial report if the grant is awarded.

  It is the responsibility of the applicant to follow-up with the Signing Official with instructions. The proposal may NOT be submitted without the signature of the Signing Official. By adding the Signing Official to the application, you are granting them access to the application.

Recommender and Co-Investigator Contacts

Enter contact information and additional details for each recommender (two required) and each co-investigator (optional). To add a recommender or co-investigator to your award record, enter their email address and click the "Add Contact" button. In the pop-up window, select the appropriate role from the drop-down menu. Complete the requested fields, including the institution of the individual. If the institution is not available in the search institution list, please add it in the Manual Institution Name field. Click "Save" when done and repeat this process for each individual.

- **Contact Information for Recommenders *(two required)*:** Applicants must provide contact information for any two individuals who will submit confidential letters of recommendation on their behalf. The selected recommenders should be familiar with the applicant's qualifications and potential for success in their proposed research. See the section "Request Letters of Recommendation" for instructions for requesting letters of recommendation.
- **Contact Information and Supporting Documentation for Co-Investigators *(optional, PDF upload of 5-page NIH-style Biosketch for each co-investigator)*:** Co-investigators are key personnel who make substantive intellectual and scientific contributions to the proposed research and share responsibility for the design, conduct, and execution of the project. Applicants may include

co-investigators whose expertise is essential to achieving the project objectives and who will play an active role throughout the award period. The roles and responsibilities of each co-investigator should be clearly described in the research plan and other application materials, as applicable.

When entering the contact information for individuals with the role of co-investigator (maximum two), you will be prompted to upload an NIH-style Biosketch (up to 5 pages).

Request Letters of Recommendation

Recommender letters should describe the candidate's qualifications and potential for contributing to regulatory science, highlighting specific skills or expertise, while demonstrating the candidate's commitment to advancing equity. Letters might also indicate the applicant's ability to implement their strategy in a timely manner and may speak about the feasibility of their approach. Letters may also choose to provide evidence of the candidate cultivating collaborative and collegial relationships.

Recommendation letters must be requested through the ProposalCentral system by adding the recommender's email address to the "Request Recommender Letter" section. Reference letters must be uploaded by the letter writer prior to submission. The following are instructions for requesting a letter of recommendation:

- In the online application, access the Request Recommendation Letters Section.
- Send an email to the recommender requesting a letter. Enter the email address of the recommender, confirm the email, and click the "+" button. A pop-up screen will appear. Verify the information and click the "Send Email" button.
- The recommender will be sent instructions on how to upload the letter. The letters must be submitted on official letterhead with a signature block as a PDF.
- Once the letter has been uploaded, it should be listed in the "Attached Documents" section as an attachment.
- Candidates can view the status of confidential letters in the system (i.e., whether or not a letter has been submitted), but not their content. It is the responsibility of the candidate to ensure that the recommendation letters are submitted on time.

It is recommended that all letters are uploaded by February 4, 2027, to ensure completion and submission by the application deadline, February 11, 2027.

Recommenders should upload their confidential letters well in advance of the deadline to allow ample time to troubleshoot any issues. Applicants are responsible for ensuring this happens and should liaise with recommenders accordingly. An application will not be considered complete without these confidential recommendation letters and cannot be submitted.

Note:

- Please ensure the recommender is listed with their contact information in the "Recommender and Co-Investigator Contacts" section.
- When requesting recommendation letters, applicants must use their recommenders' professional/institutional email accounts. The use of personal email accounts is prohibited, unless prior approval has been granted from BWF.
- An application will not be considered complete and cannot be submitted without the two recommendation letters.
- No late applications will be accepted due to letters not being uploaded.

Abstract and Lay Summary

- **Lay Abstract:** Provide a general audience summary in the text box provided. Take care to develop a well-articulated summary that the educated general public can comprehend. (Limit 3,000 characters, including spaces.)
- **Scientific Abstract:** Describe the proposed work in language that is understandable to a multidisciplinary group of scientific reviewers. (Limit 3,000 characters, including spaces).
- **Area of Work and Discipline of Project:** Select the most appropriate area of work and discipline for the project from the list provided.
- **Strategic Focus:** Following the instructions provided, indicate which strategic area of regulatory science you intend to address through your research.

Budget

- **Budget Period Detail:** Prepare an itemized budget that outlines how the funds will be utilized. Complete each of the five periods/years of the grant. List proposed research expenses in the general categories provided: Personnel, Equipment, Supplies/Materials, Meetings/Travel/Professional Development, Consultants, and Other. No more than $100,000 may be budgeted per budget period/year. The award amount is $500,000 over five years.
- **Budget Summary:** The "Budget Summary" section provides a consolidated view of the itemized budget entered in the Budget Period Detail section. Review the summarized costs to ensure they accurately reflect the proposed project expenses across the entire award period.

  In the space provided, applicants must provide a clear budget narrative that corresponds to the summarized budget totals and covers all years of requested funding. The narrative should describe the purpose and necessity of major budget items and any other significant expenses. If costs vary between years, explain the reason for those changes. The narrative should also demonstrate how the requested funds are reasonable, appropriate, and directly related to the successful completion of the proposed project.

  The information below summarizes major funding guidelines and limitations. Applicants should consult the "Terms of Grant/Use of Funds" section starting on page 6 for complete requirements and restrictions.
- **Guidelines for Personnel:**
  - Awarded institutions are allowed up to $30,000 per year to be used for the Primary Investigator's salary support, including fringe benefits, and $30,000 for any co-investigator's salary, including fringe benefits.
  - The Primary Investigator must devote at least 50% of their total effort to research-related activities to be eligible to apply for this grant. This research effort may include work supported by the IRSA award as well as unrelated research supported by other grants and institutional funding. The effort entered in the IRSA budget should reflect ONLY the percentage of effort dedicated to the proposed IRSA project. Applicants may use the budget justification to provide context regarding the PI's overall distribution of effort across their research portfolio. For example, "The PI's annual institutional salary is $150,000 (100% FTE). During the award period, 75% of their total professional effort will be devoted to research activities and 25% to teaching. Of their total research effort, 30% will be dedicated to the proposed IRSA project. Salary support requested from BWF is $25,000, with corresponding fringe benefits of $5,000. The remainder of their salary and research effort will be supported by institutional funds and other research awards."
  - There is no limit on use of the award for salary support for other laboratory personnel.
- **Budget Stipulations:**
  - No indirect costs may be charged against the grant.
  - Student tuition and fees are not allowed.
  - Student stipends are allowed.
  - Purchases of equipment should not exceed $50,000 per year and travel costs should not exceed $15,000 per year without prior written authorization by BWF.

Organizational/Proposal Assurances

Indicate whether the project includes human subjects. If so, upload the one-page approval sheet of your IRB Certification. If your certification is still 'Pending', upload the first page of your IRB application.

Publications (Three Required)

Provide information for three peer-reviewed publications or manuscripts ('manuscripts accepted with revisions' are allowed) that demonstrate your capabilities and relevant research accomplishments. You must be the first or senior author on at least one of the three publications. Any other publications, including those co-authored with your co-investigators, can be included in your bibliography section. A PDF of the full manuscript for each listed publication (reprint) must be uploaded in the Attachments section of the application portal.

Provide information on the following by clicking the blue "add" button:

- You have the option of selecting publications already provided in your professional profile. You can also add new publications by clicking the "Create New Publication" button. Add the title of the publication, authors, work type, the journal, and any other pertinent information. Adding the DOI will automatically complete the information and provide a link to the publication (if available).
- Be prepared to add a PDF of each manuscript in the "Research Plan & Attachments" section of the application.

Only THREE reprints will be allowed. If more are included, the application will be rejected out of fairness to all candidates.

Personal Statement and Project Information

- **Personal Statement *(required; 4,500 character limit, including spaces)*:** Describe your activities and interests outside of science to give the IRSA Advisory Committee a sense of your individuality beyond your scientific accomplishments. If you wish, you may also choose to describe life experiences that have influenced your work and/or address any characteristics mentioned in the RFP as we strongly encourage applications from those historically underrepresented in the research enterprise.
- **Implementation Plan *(required; 4,500 character limit, including spaces)*:** The purpose of the BWF Regulatory Science initiative is to fund investigators developing innovative, implementable solutions to regulatory problems, particularly those that improve or responsibly accelerate development of products/interventions while preserving scientific rigor, quality, and safety, and, where relevant, accounting for interindividual variation. Therefore, a critical component of application review will be the committee's assessment of how the proposed work could inform regulatory science practice, standards, guidance, policy, evaluation, and/or decision-making. Please describe your strategy and timeline for incorporating your findings into regulatory science practice. Identify the intended users or beneficiaries of the work, relevant collaborators or stakeholders, anticipated barriers or pitfalls, and the major validation and implementation steps that you envision. Direct collaboration with a regulatory authority may strengthen an application when appropriate but is not required. Clearly identify the specific regulatory problem that your project will address and avoid broad generalizations such as "speed up the drug approval process." Instead, explain specifically how the work is expected to improve the quality, efficiency, timeliness, rigor, or applicability of regulatory science and how the anticipated results will help overcome the identified problem. It is particularly important to include a timeline for implementation.
- **Facilities and Resources *(required; limit of 5,500 characters, including spaces)*:** Briefly describe the laboratory space, equipment, and other resources for research and training that will be available to the investigator(s).

Research Plan and Attachments

Applicants should provide the following by clicking the "Attach Files" button to upload the requested PDF documents:

- **Research Plan *(required as a PDF upload; no more than six pages)*:** In no more than six (6) pages (including figures, tables, graphs, and images), describe your Research Plan. It should be a complete, cohesive, and coherent scientific document that is easy to read. In the order listed below, your plan should describe:
    1. Specific aims.
    2. Background and significance. Include a statement that correlates your research to Regulatory Science.
    3. Experimental methods and procedures.
    4. Long-term objectives. If the applicant has received or applied to other sources for extended support to cover research in the area of this proposal, explain in detail how the research to be supported by BWF's award will differ from or enhance the research supported by the other sources.

It is your decision how to present your proposal, but we recommend you consider these points:

1. State the larger objective of your proposal succinctly and provide specific aims that will achieve this objective.
2. Provide a brief description of your ability to carry out the proposed project including resources available.
3. Discuss briefly the interdisciplinary and innovative aspects of your proposal.
4. Clearly describe how the proposed work will improve regulatory science and contribute to human health. Where relevant, explain how the project accounts for interindividual variation and how that may influence the evidence underlying regulatory evaluation/decision-making.
5. Place your project in a larger context to describe its impact on other areas, emphasizing its significance.

Additionally, please format the Research Plan as follows:

1. Use standard 11- or 12-point font for the text, and no smaller than a 9- to 10-point font for figures, legends, and tables.
2. Text must be single-spaced, with one inch or larger margins on all sides.
3. Number the pages of the research plan. Do not include a table of contents or appendices.
4. A reference list or bibliography of citations is optional and is not considered part of the six-page limit for the research plan.

- **Bibliography *(optional; up to four pages, PDF upload)*:** Provide a list of literature references or citations directly relevant to the research plan. The bibliography is not included in the six-page limit for the research plan and submission of a bibliography is optional. While we do not specify a preferred style for citations listed in the bibliography, we recommend using a standard style commonly used in your professional publications.
- **Publications *(three required; PDF upload)*:** Provide a PDF of each of the manuscripts listed in the Publications Section of the proposal. Only three publications or manuscripts (accepted with revisions is permitted) that demonstrate your capabilities and relevant research accomplishments can be provided. Do not combine manuscripts into one PDF; upload each manuscript as a separate PDF.

Institutional Certification and Required E-Signatures:

The applicant and Signing Official are required to certify that the application is complete and true. The following is required prior to submission and by the application deadline.

- **Applicant Signature *(required)***
- **Institutional Signing Official Signature *(required)*:** The Institutional Signing Official should be added to the application in the "Nominating Institution and Contacts" section. This individual will automatically be given edit privileges to the proposal. The person is required to login to ProposalCentral, review and/or edit the proposal, visit the "Institutional Certification & Required E-Signatures" section, and add their signature prior to the application deadline.
- **Co-Investigator Signature *(required if co-investigator is identified in application)*:** Co-investigators should have been given edit privileges to the application when added in the "Recommender & Co-Investigator Contacts" section. Co-investigators will be required to login under their account and provide their signature(s).

  Applications cannot be submitted without all signatures. Signatures must be obtained prior to the application deadline. Extensions will not be given for missing institutional signatures.

Validating Your Application

Applicants must click the "Validate" link to check for any missing required information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the next step.

Submitting Your Application

Once the application is completed and validated, proceed with submitting your application.

- Click "Submit" on the sidebar. In this section, there will be a button to submit the application. Review the instructions and click the blue "Submit" button to submit your application. Your application is not submitted until you complete this step.
- Application submissions must occur prior to February 11, 2027, at 3:00 pm (EST). The submit button will disappear after that time.
- You should receive a confirmation email once your application is submitted. If you do not receive a confirmation email, check that your application was submitted, then reach out to BWF.

Note:

- Proposals will not be accepted after 3:00 pm Eastern Standard Time on February 11, 2027. Plan to submit your application well in advance of the grant deadline to allow adequate time to collect recommendation letters, required E-Signatures, and to troubleshoot any issues. No exceptions will be granted for missing recommendation letters or signatures. Only grant proposals submitted through ProposalCentral will be accepted. NO EXCEPTIONS OR EXTENSIONS WILL BE GRANTED.
- After the deadline, applicants with incomplete proposals and those not adhering to instructions will be disqualified without prior notice. Do not include a cover letter or supplemental materials. If extra materials are included, the application will be rejected out of fairness to all applicants.

Accessing a Saved Application

To access a saved proposal, login to the ProposalCentral system. Click the proposals tab to see a list of in progress or submitted proposals, along with the status.

Correcting a Submitted Application

After a full application proposal has been submitted, applicants have the option to unsubmit it to make changes, if necessary, only if: 1) the application deadline hasn't passed; or 2) BWF has not already routed the application to a committee for review.

In the event that an applicant needs to edit an application, please review the instructions on page 26 for "Unsubmitting An Application" in the "How to Create an Application Using Proposal Central" guide accessible here.