

INNOVATION IN REGULATORY SCIENCE AWARDS

Application Instructions

Deadline: February 7, 2025

KEY DATES

Application deadline	February 7, 2025, 3:00 pm EST
Finalists notified	By end of April 2025
Finalist interviews	June 3-4, 2025
Notice of award	By July 31, 2025
Award start date	September 1, 2025
Award end date	August 31, 2030

START EARLY AND PLAN AHEAD!

- Applications will not be accepted after 3:00 pm EST on February 7, 2025. **The online application system shuts down automatically at the deadline and the SUBMIT button will not process a submission.**
- A completed proposal consists of data entry fields submitted through the online module plus a series of PDF attachments, a confidential letter of support from two recommenders, and approval from the institution's signing official.
- Applications **will require** a signature from the institutional signing official. The signatory official will receive an email once their contact information is added to the proposal. The candidate should ideally follow-up with the signing official and provide instructions. The signing official should "sign off" by the application deadline of February 7, 2025, at 3:00 pm.
- 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.
- All attachments must be uploaded as Adobe 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.

OVERVIEW OF PROPOSAL ELEMENTS

Overview of Proposal Elements

A. To be completed online:

1. Lay abstract (limit of 3000 characters, including spaces)
2. Scientific abstract (limit of 3000 characters, including spaces)
3. Budget
4. Personal Statement from primary applicant (limit of 4500 characters, including spaces)
5. Implementation Plan (limit of 4500 characters, including spaces)
6. Facilities and Resources (limit of 5500 characters, including spaces)

B. To upload to the application as a PDF:

1. NIH Biosketch (for primary applicant and each co-investigator)
2. Research Plan (6-page limit, not including Bibliography)
3. Bibliography (optional)
4. Organizational Assurances (optional, one-page limit)
5. Submitted Reprints (three required)

C. Recommendation Letters – confidential (two required)

D. Institutional Signing Official Signature Required (prior to deadline)

STEPS TO THE APPLICATION PROCESS

To begin a proposal, applicants should use ProposalCentral. Proposals must be submitted by February 7, 2025, at 3:00 p.m. (ET). ProposalCentral is an application and grants management system utilized by multiple funders. Applicants may already have an account on the site. New users will need to create an account. To access ProposalCentral use the link below:

<https://proposalcentral.com>

Proposals that are not in compliance with instructions will be rejected out of fairness to all applicants.

Proposals will not be accepted after February 7, 2025. The online application system shuts down automatically at the deadline. Plan to submit your application well in advance of the grant deadline to allow adequate time to troubleshoot any issues. **NO EXCEPTIONS OR EXTENSIONS WILL BE GRANTED.**

REGISTERING ON PROPOSALCENTRAL

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 at a later time. 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 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. For a full summary of instructions for registering as a ProposalCentral User visit the instructional guide accessible at this link, <https://docs.proposalcentral.com/RegUser.pdf>.

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 they 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 orcid.org for additional details. To start an application from the professional profile, locate the red “Create New Proposal” button. For a full summary of instructions on creating an application in ProposalCentral, review the instructional guide accessible at this link, <https://docs.proposalcentral.com/CreateApp.pdf>.

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 Award and click the “Apply Now” button.
- Verify that an application is being created for the Program: Innovation in Regulatory Science Award, enter the project title and hit “Save.”
- Complete the application now or save and revisit later.

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 of the Innovation in Regulatory Science Award. 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). Click “Save” to be able to return to the proposal at a later time. Answer any additional questions on the page.

Download Templates and Instructions:

In this section, candidates can download the IRSA RFP and other instructions for completing the application.

Enable Other Users to Access this Proposal:

This section allows applicants to grant access to others that would like to have access to 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 proposal. If there are other individuals assisting you in preparing, editing, or submitting the proposal, they must also create a user account for ProposalCentral following the instructions on page 3.

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):

- **Institution:** This is the institution where the lead applicant currently holds a position. It is likely that the institution already has a profile on the system. If the institution does not have a profile, [contact technical support for assistance](#). If your institution is not listed on 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.
- **Contact Information:** Position Title, Academic Rank, Primary Job Function, Department, Address, City, State, Zip, Country, Work, Mobile

- **Degree Information:** Please enter your degree information in the fields provided to include the degree type, year awarded, and awarding institution for each degree awarded including bachelors, masters, and doctoral degrees
- **PI Institution Type:** Please indicate whether or not the nominating institution for which you’re applying on behalf 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** (required as PDF upload)
Upload a current NIH-style Biosketch as a PDF

Candidates are not required to have an ORCID ID to submit an application. However, it is recommended that you create an ORCID ID account and link it to your ProposalCentral account. ORCID ID is a persistent digital identifier that is unique to individual researchers, where they can keep their CV information current and share with other systems. Visit orcid.org for additional details.

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.

- **Demographic Data** (for statistical use only)

Nominating Institution and Contacts:

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.

- **Institutional Certification and Signature from Signing Official**

Candidates MUST obtain approval from the institution that nominated them. 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 Institutional or Signing Official

PROPOSAL ELEMENTS – CONTINUED

should be added in this section, including the Finance Officer. An email will be generated to the Institutional Officer/Signing Official and Finance Officer notifying them that an application is in progress. The Institutional/Signing Official will need to certify the applicant's eligibility for the award, that the institution approves the application submission, and 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 official to the application, you are granting access to the application.

Key Personnel and Other Contacts:

Contact information and additional details on the following individuals should be provided:

- Each individual preparing a letter of recommendation (two required; letters are requested in the “Request Recommendation Letter” section)
- Any co-investigators (up to two; NIH Biosketch also required)

To add key personnel, enter the email address of the individual 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 key personnel. If the institution is not available in the search institution list, please add in the Manual Institution Name field. Click “Save” when done.

For any co-investigators (maximum two), upload a NIH Biosketch (limit 5 pages) or two-page CV.

Request Letters of Recommendation:

Two recommendation letters are REQUIRED from individuals who are familiar with the applicant's qualifications and MUST be uploaded to your application by the letter writers. These letters must not be viewed by the applicant. No more than two recommendation letters may be provided.

Recommender letters should describe the candidate's qualifications and potential for contributing to regulatory and medical 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. Instructions for requesting recommendation letters can be found here:

- Confidential letters must be requested by the candidate by using the “send email” function in the online application.
- Candidates can view the status of confidential letters 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. 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. It is recommended that the letters be uploaded a week prior to the application deadline to allow ample time for the letter completion.
- The letters must be submitted on official letterhead with a signature block as a PDF.

To request the letter of recommendation:

From within the online application, access the Request Recommendation Letters Section:

1. 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.
2. The mentor will be sent instructions on how to upload the letter. Once the letter has been uploaded, it should be listed in the Attached Documents section as an attachment. Letters are confidential and cannot be viewed by the candidate.
3. Recommenders should also be listed with contact information in the Key Personnel section.

Abstract and Lay Summary:

Provide the following:

- **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

PROPOSAL ELEMENTS – CONTINUED

multidisciplinary group of scientific reviewers. (Limit 3,000 characters including spaces).

- **Area of Work and Discipline of Project:** Select the most appropriate 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:

Prepare a budget that explains 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 (e.g., personnel, equipment, consumable supplies, and travel) for each period of the award (total of five). No more than \$100,000 may be budgeted per budget period/year. The award amount is \$500,000 over five years.

Guidelines for Personnel: Award recipients are allowed up to \$30,000 per year to be used for primary investigator salary support, including fringe benefits, and \$20,000 for any co-investigator's salary, including fringe benefits. 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 \$20,000 per year and travel costs should not exceed \$8,000 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 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.

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

- Select publications provided in your professional profile or add new publications by clicking the "New Publications" 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 able).
- Be prepared to add a PDF of the reprint to the Attachments section of the application.

Only THREE reprints will be allowed. If more are referenced, the additional reprints will be removed.

Personal Statement & Project Information:

Personal Statement (required; 4500 character limit, including spaces): Describe your activities and interest 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; 4500 character limit, including spaces): The purpose of the BWF Regulatory Science initiative is to fund investigators who are developing innovative and implementable solutions to regulatory problems, especially those solutions which advance equitable outcomes. Therefore, a very important part of the review of your application will be the committee's understanding as to how your findings will change regulatory approval and advance equitable approaches. Please provide a paragraph that explains your strategy and timeline for moving your findings towards regulatory approval for their use in regulatory decision making. You should include any pitfalls and the major validation steps that you envision. Identify the specific regulatory problem that your project will address while avoiding generalizations, such as "speed up the drug approval process." Highlight how you expect your results will overcome the problem that you have identified. It is particularly important to include a timeline of your implementation plan.

Facilities and Resources (required; limit of 5500 characters, including spaces): Briefly describe the laboratory space, equipment, and other resources for research and training that will be available to the investigator(s).

PROPOSAL ELEMENTS – CONTINUED

Research Plan and Attachments:

Research Plan (required; six-page limit – not including references): 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:

- Specific aims.
- Background and significance. Include a statement that correlates your research to Regulatory Science.
- Experimental methods and procedures.
- 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:

- State the larger objective of your proposal succinctly and provide specific aims that will achieve this objective.
- Provide a brief description of your ability to carry out the proposed project including resources available.
- Discuss briefly the interdisciplinary and innovative aspects of your proposal.
- Clearly describe how you will advance approaches that promote equity in clinical outcomes.
- Place your project in a larger context to describe its impact on other areas, emphasizing its significance.

Format the Research Plan as follows:

- 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.
- Text must be single-spaced, with one inch or larger margins on all sides.

- Number the pages of the research plan.
- Do not include a table of contents or appendices.
- A bibliography is optional and is not considered part of the six-page limit for the research plan.

Bibliography (optional; up to two pages): An optional bibliography may be uploaded with a maximum of two pages.

Sign and Print:

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, edit the proposal, visit the Sign and Print 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 Key Personnel Section. Co-investigators will be required to login under their account and provide the signature.

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.

Validate:

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.

SUBMISSION PROCESS

Once the application is complete, proceed with the following steps:

- Click “Validate” on the sidebar to see if any errors are identified. All information must be provided prior to application submission.
- If there are no missing items in the application, click on the SUBMIT link on the sidebar. Click the blue SUBMIT button. The application is NOT submitted until you complete this step.
- Application submissions must occur prior to February 7, 2025 at 3:00 pm (EST). The submit button will disappear after that time. Applicants should receive a confirmation email once their application is submitted. If you do not receive this email, please reach out to BWF.

Proposals will not be accepted after 3:00 pm Eastern Time on February 7, 2025 from the applicant. Plan to submit your application well in advance of the grant deadline to allow adequate time for signatory official approval 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.

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.

Correcting a Submitted Application:

After a 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
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 27 for “Unsubmitting An Application” in the “How to Create an Application Using Proposal Central” guide accessible at this link <https://docs.proposalcentral.com/CreateApp.pdf>.

Questions?

The following are available on the BWF website:

- [Innovation in Regulatory Science](#)
- [FAQs](#)

For programmatic questions related to the Innovation in Regulatory Science Awards, please contact:

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