

# INNOVATION IN REGULATORY SCIENCE AWARDS (IRSA)

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## **Request for Proposals:**

February 10, 2023 by 3:00 pm (ET)

BURROUGHS  
WELLCOME  
FUND 

## **TABLE OF CONTENTS**

<b>Key Dates and Program Background</b>	<b>3</b>
<b>Eligibility Requirements</b>	<b>4</b>
<b>Important Notes</b>	<b>5</b>
<b>Selection Process</b>	<b>5</b>
<b>Instructions on How to Prepare and Submit a Complete Proposal</b>	<b>6</b>
Application Process	6
Proposal Elements	6
How to Submit a Proposal	6
Submission Process	7
<b>Terms of Grant / Use of Funds</b>	<b>8</b>

# KEY DATES

<b>Application deadline</b>	February 10, 2023 (3:00 pm ET)
<b>Finalists notified</b>	By the end of April 2023
<b>Finalist interviews</b>	June 6-7, 2023
<b>Notice of award</b>	July 2023
<b>Awards begin</b>	September 1, 2023

## PROGRAM BACKGROUND

The Burroughs Wellcome Fund (BWF) recognizes Regulatory Science as an important yet underfunded area of research. With this initiative, BWF aims to provide research support to stimulate innovation in this area.

The process of translating biomedical discoveries into new therapies has become increasingly complex in light of evolving science and technology, and requires that the science of regulation keep up with the advances in biomedical science and technology. For example, existing animal models of human disease are often poor predictors of efficacy of new therapeutic approaches in humans. As new technologies produce new types of preclinical models, innovation is needed in the evaluation of these models to justify movement into clinical studies. Although numerous reports<sup>1</sup> have documented the importance of this area of research to the future of the biomedical enterprise, it remains inadequately supported.

Regulatory science has been defined as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.”<sup>2</sup> Regulatory science has become a centerpiece of the Food and Drug Administration’s (FDA) strategy for fostering innovation, and the academic and foundation communities have been called to take an active role in building this emerging field. We therefore strongly encourage investigators to address regulatory science in areas of the FDA’s strategic priorities including but not limited to: regenerative medicine (including gene therapy), artificial intelligence and machine learning, digital health, reduction of animal testing, and model-informed product development.

<https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science-report>

BWF’s Innovation in Regulatory Science Awards provides \$500,000 over five years to academic researchers developing new methodologies or innovative approaches in regulatory science that will ultimately inform the regulatory decisions FDA and others make. This would necessarily draw upon the talents of individuals trained in mathematics, computer science, applied physics, medicine, engineering, toxicology, epidemiology, biostatistics, systems pharmacology, and food safety and nutrition to name a few.

1. FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology, FDA Science Board, 2007; Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products, Food and Drug Administration 2004; Building a National Framework for the Establishment of Regulatory Science for Drug Development, Institute of Medicine Workshop Report; Advancing Regulatory Science at the FDA, 2011.
2. FDA, 2010. NIH and FDA Announce Collaborative Initiative to Fast-track Innovations to the Public.

# ELIGIBILITY REQUIREMENTS

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; persons with disabilities; persons from disadvantaged backgrounds (see <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html> for examples); and individuals who identify as LGBTQIA+.

The [FAQs](#) may also provide eligibility clarification.

- Candidates may self-nominate but need to obtain approval by an official for sponsored programs at the institution where the work will be performed.
- 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 be based at a non-profit institution [501(c)(3) or equivalent] in the U.S. or Canada.
- Candidates must hold a faculty position, tenure-track or non-tenure track, or adjunct faculty position at an accredited, degree-granting institution in the United States or Canada; grants are made to the institutions on behalf of the award recipients.
- Candidates must be an investigator at the adjunct, assistant, associate, or full professor level.
- 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, C44, C-10, or C-20 work permits/visas). If a grant is awarded and your 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 by their visa status. Your institution must verify your immigration status as part of your application.
- Postdocs are not eligible.
- Candidates who currently hold a BWF award are not eligible.
- Candidates may only submit one application per award cycle.
- Applications must be submitted by the principal or primary investigator (PI). The PI may have up to a total of two co-investigators. Co-investigators need not be at the same institution; however, one person must be designated as the primary investigator, and must meet all eligibility requirements.
- Candidates must agree to the Terms of Grant.

## IMPORTANT NOTES

Grants can only be made to non-profit degree-granting institutions [501(c)(3) or equivalent] in the U.S. or Canada on behalf of the award recipient.

Primary investigators are required to devote no less than 50% of their time to research-related activities.

Indirect costs may not be charged against BWF grants.

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

## SELECTION PROCESS

The [Regulatory Advisory Committee](#) will review all proposals, select finalists to invite for an interview, and make recommendations for awards to the [BWF Board of Directors](#).

Selection will be based on the creativity of the proposal and its potential to lead to significant innovation in regulatory science, as well as on the appropriateness of the environment in which the project is to be conducted, and its potential impact on the careers of investigators. The translation of possible results of the research to improving the regulatory process will be an important consideration in the selection process.

Selected finalists will have the opportunity to present their research during interviews with the advisory committee.

All eligibility requirements must be met.

Candidates not selected may reapply in the next award cycle, provided they still meet the eligibility requirements. **BWF does not provide critiques of unfunded proposals.**

# INSTRUCTIONS ON HOW TO PREPARE AND SUBMIT A COMPLETE PROPOSAL

## Application Process

Start early—applications must be submitted by the deadline, no exceptions will be made.

- 1. Proposals.** Interested candidates who meet the eligibility criteria may submit one online proposal through ProposalCentral by **February 10, 2023 (3:00 pm ET)**. In brief, the application includes applicant information (to be completed within the grant portal), proposal elements which must be uploaded as a PDF, plus the letters of recommendation to be uploaded confidentially by recommender.
- 2. Interviews.** A selected group of finalists will be invited to interview. Finalists must be available to interview virtually on **June 6-7, 2023** at the Burroughs Wellcome Fund in Research Triangle Park, North Carolina. Notification will be sent to finalists by the end of April 2023.

## 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
- B.** To upload to the application as a PDF:
  1. NIH Biosketch (for primary applicant and each co-investigator)
  2. Personal Statement from primary applicant (template required – 1-page limit)
  3. Implementation Plan (template required, one-page limit)
  4. Research Plan (6-page limit)

5. Bibliography (optional)
6. Facilities and Resources (template required, one-page limit)
7. Submitted Reprints (three required)

- C.** Recommendation Letter(s) – confidential (two required)
- D.** Institutional Signing Official Signature Required (prior to deadline)

All template forms can be found [here](#).

All communications, including the invitation to interview and declinations, will be made through email.

BWF does not provide critiques or written comments of unfunded proposals.

## How to Submit a Proposal

All proposals must be submitted through ProposalCentral, a common application system shared by multiple funders.

To begin a proposal submission use this link: [proposal](#)

New users will be required to set-up a profile on ProposalCentral. Existing users may log-in with their existing account.

*Detailed instructions on how to submit a proposal and the proposal elements are available on the BWF website.*

Two confidential letters of recommendation are required for the application. Note that it is the responsibility of the applicant to ensure that the confidential letters are submitted by the deadline due date. An application will not be considered complete without these confidential recommendation letters. Letters must be requested through the application system and the recommender can upload the letters to the application confidentially.

Applications are not required to be completed in one sitting.

## Submission Process

Detailed instructions on the submission process are available in the “IRSA Application Guide for ProposalCentral” on the BWF website.

### Note:

Proposals will not be accepted after February 10, 2023. The online application system shuts down automatically at the deadline and the SUBMIT button will no longer process a submission. 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.**

After the deadline, applicants with incomplete proposals and those not adhering to instructions will be disqualified without prior notice.

Only proposals submitted through ProposalCentral will be accepted.

It is the responsibility of the applicant to ensure that the confidential recommendation letters have been uploaded to their application and submitted by the deadline. Late submissions will not be accepted.

## Questions?

Please review our online [Frequently Asked Questions](#) first. Eligibility inquiries should be directed in advance to BWF program staff by contacting:

Tammy Collins, PhD, Program Officer  
[tcollins@bwfund.org](mailto:tcollins@bwfund.org)

Melanie Scott, Senior Program Associate  
[mescott@bwfund.org](mailto:mescott@bwfund.org)

# TERMS OF THE GRANT/USE OF GRANT FUNDS

## **Indirect costs may not be charged against the grants.**

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 ultimate translation of those results into improving the regulatory process.

Grants can only be made to non-profit degree-granting institutions [501(c)(3) or equivalent] in the U.S. or Canada on behalf of the award recipient. The institutions are responsible for disbursing the funds and for maintaining adequate supporting records and receipts of expenditures.

Award recipients must provide BWF with an annual progress report, and institutions must provide an annual financial report, using forms provided by BWF. Continued funding will depend on both the timely submission of these reports and their favorable review by BWF and its program advisory committee.

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. Award recipients may not hold concurrent BWF awards.

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. The remainder of the grant is to be used for expenses relating to the named investigator's proposed research. BWF does not set or cap the salary level of its awardees, nor does it require a minimum amount of the award to be used to cover salary. An institution may supplement the grantee's salary to a level consistent with its salary scale. There is no limit on use of the award for salary support for other laboratory or clinical personnel working with the grantee. Student tuition and fees are not allowed.

Support allocated for research is under the control of the award recipient and may be used flexibly for such items as equipment, consumable supplies, travel to scientific meetings, and laboratory personnel working with the award recipient. Prior approval by BWF is required when, within an award year, purchases of equipment exceed \$20,000 or travel costs exceed \$8,000.

During the award period, unused research funds may be carried over to the succeeding year. Any unused funds that exceed 5% of the original grant awarded or \$25,000 (whichever is less) held by institutions when grants expire or are terminated must be returned to BWF, unless the Fund has granted prior permission to retain the funds. Award recipients may receive a no-cost extension of up to 24 months; requests explaining why an extension is needed must be submitted in writing at least four months prior to the end of the award.

Awards may be transferred to another institution only with the written approval of BWF. Requests explaining why a transfer is needed must be submitted by the grantee in writing at least three months prior to the transfer date.

Scientific publications or presentations that result from these awards must acknowledge the award recipient'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.

BWF will not retain any rights to published results, intellectual property, or patents that result from the research. Award recipients should follow their institutions' patent, copyright, and intellectual property policies regarding discoveries that result from research conducted under these awards.

Award recipients are expected to adhere to all federal, state, and local regulations regarding the participation of human subjects, and the use of animals, radioactive and hazardous materials, and recombinant DNA in their research projects. 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.

Award recipients should share scientific findings in a timely manner via the standard means of scientific communication, including publications and/or presentations in scientific forums. BWF encourages, but does not require, that awardees publish in open access journals.

Grants will provide up to \$500,000 over a five-year period and are expected to begin in September 2023.