

# INNOVATION IN REGULATORY SCIENCE AWARDS (IRSA)

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**Request for Proposals:**

March 15, 2017

BURROUGHS  
WELLCOME  
FUND 

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# KEY DATES

<b>Application deadline</b>	March 15, 2017
<b>Finalists notified</b>	May 12, 2017
<b>In-person interviews</b>	June 20-21, 2017
<b>Notice of award</b>	Late July 2017
<b>Awards begin</b>	September 1, 2017

## PROGRAM BACKGROUND

The Burroughs Wellcome Fund identified Innovation in Regulatory Science as an important underfunded area and with this initiative has chosen to provide financial support to stimulate research efforts 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. Over the last decade, numerous reports<sup>1</sup> have documented the importance of this area of research to the future of the biomedical enterprise, however it remains inadequately supported.

Regulatory science has been defined as the “development and use of new tools, standards, and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy, and quality.”<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 product manufacturing & quality, and food safety & applied nutrition:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf>

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

To understand the expectations of the Innovation in Regulatory program, it is important to read the eligibility requirements below, in addition to the proposal elements, terms of grant, and selection criteria prior to taking the eligibility quiz. BWF must be notified of changes related to any of the eligibility requirements.

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., 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; grants are made to the institutions on behalf of the award recipient.
- 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.
- 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. If you are invited to submit a full application, 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 submit only one application.
- 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

BWF strongly encourages applications from women and underrepresented minorities, including Blacks or African Americans, Hispanics or Latinos, Native Americans, Alaskan Natives or Native Hawaiians.

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 through in-person interviews before the advisory committee at BWF's headquarters in Research Triangle Park, NC.

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—occasionally your resources may be unavailable! 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 BWF's Internet Grant Application Module (IGAM) by **March 15, 2017**. In brief, the application includes applicant information (to be completed within the grant portal), proposal elements which must be uploaded as one PDF, plus 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 in-person on **June 20-21, 2017** at the Burroughs Wellcome Fund in Research Triangle Park, North Carolina. Notification will be sent to finalists by May 12, 2017.

Proposal Elements:

**A.** One PDF uploaded with the following documents (in this order) and named as “**Last Name, First Name – IRSA Application**”:

- Signature Page form (*required; template provided*)
- Primary (*required*) and Co-investigator/s (*optional*) NIH Biosketch/s
- Personal Statement-nonscientific (*required; one page; template provided*)
- Implementation Plan (*required; one page; template required*)
- Scientific Abstract (*required; one-page limit; template provided*)

- Research Plan (*required; six-page limit*) – *not including references*
- Facilities and Resources (*required; template provided*)
- Budget (*required; template provided*)
- Reprints (*three required*)
- Institutional Certification Form (*required; template provided*)

**B.** Two Recommendation Letters – to be uploaded confidentially by recommenders.

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

First complete the eligibility quiz to determine if you are eligible to apply. If applicant meets the eligibility criteria, they will be allowed to access the application form.

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

To return to a proposal already in progress you must use this link: [saved proposal](#)

It is recommended that applicants bookmark this page to return to a proposal in progress. Using the first link of the two immediately above will return you to the eligibility quiz.

## Proposal Elements

All proposals must be submitted through the Burroughs Wellcome Fund Grant Application System IGAM application including a single uploaded PDF attachment, and confidential recommendation letters to be uploaded by the letter writer.

**Note that it is the responsibility of the applicant to ensure that the confidential letters are submitted by the deadline due date. Each element of the proposal must be completed before the application can be submitted, and an application will not be considered complete without the confidential recommendation letters.**

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

All attachments must be uploaded as Adobe Portable Document Format (PDF) files.

The following supporting materials are required (All documents must have a minimum 11 point font with one-inch margin.)

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

The required proposal materials listed below must be completed according to the detailed instructions. Standard word processing software can be used to prepare the materials. Templates where provided must be used and are available for download in Word and Portable Document Format (PDF). Supporting materials must be combined into one single PDF file, *in the order shown*, and named in the format of: **Last Name, First Name – IRSA Application**.

### A. Proposal Materials as one PDF attachment as follows:

#### 1. Signature Page *(required; template provided)*

Using the Signature Page template, enter the contact information for the investigator(s), obtain the signatures, and include it as the first page of the combined PDF file. Candidates are responsible for ensuring that the information on the Signature Page matches the information entered into the online application.

#### 2. Primary Investigators NIH style Biosketch *(required)* and Co-Investigators' NIH biosketch/s *(optional)*

Provide your biographical information using the current NIH Biosketch template.

#### 3. Implementation Plan *(required; one page; template required)*

The purpose of the BWF Regulatory Science initiative is to fund investigators who are developing innovative and implementable solutions to regulatory problems. Therefore, a very important part of the review of your application will be the committees' understanding as to how your findings will change regulatory approval. Please provide a paragraph that explains your strategy and time line 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.

#### 4. Personal Statement *(required; one page; template provided)*

Using the template provided in the forms section, describe your activities and interests outside of science to give the IRSA Advisory Committee a sense of your individuality beyond your scientific accomplishments.

#### 5. Scientific Abstract *(required; one-page limit; template provided)*

Using the Scientific Abstract template, describe the proposed work that is understandable to a multidisciplinary group of scientific reviewers. Do not add additional pages.

**6. 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 innovation aspects of your proposal.
- Place your project in a larger context on 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-half 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.

**7. Facilities and Resources** (*required; template provided*)

Using the Facilities and Resources template, briefly describe the laboratory space, equipment, and other resources for research and training that will be available to the investigator(s).

**8. Budget** (*required; template provided*)

Using the Budget template, prepare a budget that explains how the funds will be utilized, to include the following:

- List proposed research expenses in general categories (e.g., equipment, consumable supplies, and travel) for each period of the award (total of five) and as an overall summary on the final page.

Budget stipulations:

- No indirect costs may be charged against the grant.
- Student tuition and fees are not allowed.
- Student stipends are allowed.
- Award recipients are allowed up to \$30,000 per year to be used for primary investigator salary support, 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.
- Purchases of equipment should not exceed \$20,000 per year and travel costs should not exceed \$8,000 per year without written authorization by BWF.

**9. Reprints** (*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 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.

**10. Institutional Certification** (*required; template provided*)

The primary investigator must obtain approval from the institution where the work will be performed. Applications must 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), as indicated

by submission of a completed and signed Institutional Certification Form. Candidates should complete the application information near the top of the form and have the institutional signing official complete the remainder of the form, including the signature. A completed Institutional Certification Form must be included in the combined PDF file.

## B. Letters of Recommendation

Two recommendation letters from individuals who are familiar with the applicant's qualifications are required 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. The letter should also describe the research environment in which the candidate is working. Letters might also indicate the applicants ability to implement their strategy, and in a timely manner.

Confidential letters must be requested by the candidate by using the "send email" function in the online application. For detailed instructions, refer the recommender to this link on our website: <http://www.bwffund.org/grant-programs/regulatory-science/innovation-regulatory-science/recommender-instructions>

Candidates can view the status of confidential letters on 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.*

- The letters can be created in any word processing software, but must be converted to a PDF file prior to uploading.
- The letters must be submitted on official letterhead with a signature block.
- Each recommender must individually upload his/her recommendation letter before the application can be submitted. For this reason, the recommenders should upload their PDF file well before the application deadline. Applications cannot be submitted without the recommender's letters.

## Submission Process

Click the "Review Your Application" on the Attachments tab to see if any errors are identified in your application. All information must be provided before the "SUBMIT" button is available. Click the "SUBMIT" button to transmit the application. An automated message will confirm that the application was successfully submitted.

### Note:

Proposals will not be accepted after March 15, 2017. 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 preproposals and those not adhering to instructions will be disqualified without prior notice.

Only proposals submitted through BWF online application website IGAM 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:

Rusty Kelley, Ph.D. Program Officer  
[rustykelley@bwffund.org](mailto:rustykelley@bwffund.org), 919-991-5120

Tiffany Taylor, Program Associate  
[ttaylor@bwffund.org](mailto:ttaylor@bwffund.org), 919-991-5116

Ruth Reynolds, Programs Assistant  
[rreynolds@bwffund.org](mailto:rreynolds@bwffund.org), 919-991-5129

# 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 are made to [501(c)(3) or equivalent] institutions in the U.S. or Canada on behalf of the named award recipients. 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.

No more than \$30,000 of the award may be used annually for the primary investigator's, and no more than \$20,000 may be used annually for all co-investigator/s salary support, including fringe benefits. 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 (greater than \$500) 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 2017.