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Table of Contents

External Research Grants Quick Reference Guide

Mission

The Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) External Research Grants Program for U.S. Investigators supports the advancement of scientific knowledge regarding BIPI products and therapeutic areas of interest by supporting novel research proposals in areas of scientific interest to BIPI.

Overview of External Research Grants Program

The External Research Grants Program is designed to enable research that has the potential to improve the treatment of disease, patient outcomes, and the quality of health care. Support is awarded based on the scientific merit of each proposal received.

The External Research Grants Program is offered to all U.S. academic and community-based scientists, individually or through consortia. This program allows investigators to submit proposals for consideration where they may independently execute research as investigator-initiated studies (IIS) or work collaboratively with BIPI in external collaborative research (ECR).

BIPI does not assume regulatory responsibility for either type of external research, and thus investigators are expected to serve as Sponsor-Investigator for either IIS or ECR studies. External research must be independently conducted in accordance with local regulatory, legal, and ethical guidelines.

In addition to unsolicited requests, BIPI may announce specific requests for proposals (RFP) to notify qualified investigators that BIPI is interested in receiving proposals for support consideration.

About the External Research Program

- BIPI responds to requests for support of external research through submission via the online grant portal **Lectrona** by clicking on the "Apply for External Research Funding" module
- Investigators serve as Sponsor-Investigators for both IIS and ECR studies
    - Investigators and their institutions/organizations, must be in good standing with BIPI, relating to any current contractual obligations (e.g., ongoing studies) and in compliance with all applicable laws and regulations
- Studies can have interventional or non-interventional (observational) designs
- Pharmacovigilance reporting is required for studies when applicable
- Scope of the study proposal must be aligned with predefined disease areas of interest
    - BIPI may consider applications for studies outside the approved indication: if this application is approved, the investigator will be requested to file an IND with the FDA
- Financial support and/or provision of BIPI drug supply may be requested
    - Budgets will be subject to fair market value analysis
- In the event of approval, a fully executed contract between BIPI and the institution of the Sponsor-Investigator must be in place before any financial support or drug supply are provided

Frequently Asked Questions-Application Process

Am I required to apply online?

- BIPI requires applications to be submitted via an online grant portal **Lectrona**. Applications received through other means will not be considered for review.

Can BIPI personnel submit my application for me?

- No, the Sponsor-Investigator must submit the application via **Lectrona** to ensure the submission is completed independently and in an unsolicited manner.

Who may apply and participate in BIPI-funded external research?

To be considered for support, the investigator must fulfill the following requirements:

- Applicants must be U.S. academic or community-based scientists (MD, DO, other qualified HCP, or PhD), individually or though consortia
- Assume all legal and regulatory responsibilities as a Sponsor-Investigator
- Submit a well-written proposal supported by data and aligned with BI areas of interest
- Possess the scientific, technical, and operational capabilities to conduct the study and data analysis, including statistical support
- Be able to submit an Investigational New Drug Application (IND)/Clinical Trial Application (CTA), if necessary
- Deliver regular study status updates to BIPI according to agreed upon timelines

- Provide BIPI and health authorities with pharmacovigilance reporting
- Upon study completion, provide the final study report, draft publication(s), and reconciliation of drug and expenditures to BIPI in a timely manner

May I assign a delegate to apply on my (Sponsor-Investigator's) behalf?

Yes, you may apply on behalf of the Sponsor-Investigator, providing the Sponsor-Investigator's information within the application as requested.

What if I enter false information?

Providing false information may result in the immediate disqualification of your current proposal as well as previous or subsequent proposals.

What is the difference between external research opportunities (IIS and ECR)?

IIS	• Sponsor-Investigator independently proposes and conducts the research o BIPI does not provide any feedback on the study proposal and does not provide operational support • Grant funding to support preclinical (*in vitro* or *in vivo* animal), clinical, or health outcomes research studies
ECR	• Sponsor-Investigator and BIPI work collaboratively on the research proposal o Sponsor-Investigator may propose the research, but BIPI contributes to the creation of the study design, which may include but is not limited to feedback on the study design, protocol, execution, analysis, and publication of the results • Grant funding to support clinical or health outcomes studies

What types of research proposals are acceptable?

- Grant funding to support preclinical (*in vitro* or *in vivo* animal), clinical (interventional and non-interventional), or health outcomes research studies
- ECR is limited to the conduct of clinical research (e.g. observational research, including prospective studies, registries, and retrospective analyses)

Who holds the study-related responsibilities for external research opportunities offered at BIPI versus company-sponsored research?

	External Research		**Company-Sponsored**
	Investigator Initiated	**External Collaborative**	
Regulatory responsibility	Investigator	Investigator	BIPI
Objectives and design	Investigator	Collaborative	BIPI
Protocol development	Investigator	Collaborative	BIPI
Study execution/conduct/ monitoring	Investigator	Collaborative	BIPI
Data analysis	Investigator	Collaborative	BIPI
Publications	Investigator (BIPI review for accuracy)	Collaborative	BIPI

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What is required for submitting a synopsis versus a full proposal?

An applicant has the option to submit a synopsis or full proposal. A synopsis is an abbreviated application used to gauge BIPI's interest in the research study. If a synopsis has been submitted and is approved, the investigator will be invited to submit a full proposal for further review and consideration. This entails completing the additional study and budget information, as listed in the chart below. Synopsis approval does not guarantee approval of the subsequent full proposal.

It is not required to first submit a synopsis; an applicant may complete a full proposal application if desired. Ultimately, funding/drug support decisions can only be made upon BIPI's review of a full proposal.

	Synopsis	Full Proposal
Sponsor-Investigator Information	• Contact Information	• Contact Information
Study Outline	• Study Title • Currency • Therapeutic Area/Indication • Study Type • Type of Support Requested (financial and/or drug) • Drug Supply Information • Total Study Cost • Study Setting/Design • Number of Planned Sites/Locations • Cooperative Study Group Involvement • Randomization/Blinding • Target Patient Enrollment Number • Scientific Rationale and Medical Need • Study Hypothesis • Primary Objective/Endpoint • Treatment Plan/Dosing Regimen	• Study Title • Currency • Therapeutic Area/Indication • Study Type • Type of Support Requested (financial and/or drug) • Drug Supply Information • Study Setting/Design • Number of Planned Sites/Locations • Cooperative Study Group Involvement • Randomization/Blinding • Target Patient Enrollment Number • Scientific Rationale and Medical Need • Study Hypothesis • Primary Objective/Endpoint • Treatment Plan/Dosing Regimen) • Detailed Budget (personnel, study/lab supplies, analyses/reports, detailed patient/subject costs, study start up fees, other fees, overhead) • Stage of Disease/Line of Treatment • Major Inclusion Criteria/Exclusion Criteria • Additional Objectives/Endpoint • Publication Plan
Biometry/Statistics	• Statistical Methods	• Statistical Methods • Sample Size Calculation and Justification
Study Timelines	• Planned Total Study Duration	• Planned Date for Study Initiation • Planned Recruitment Time • Planned Follow up Duration • Planned Total Study Duration
Required Attachments		• Confidentiality Disclosure Agreement • Feasibility Check Form • **Signed/Dated** CV incl. References and Publications (pdf only)

What documents does BIPI require prior to the start of my study?

These documents include a fully executed contract between BIPI and the investigator's institution, regulatory documents (IND or exemption), and copy of institutional review board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval.

Is the application process the same if I am requesting study drug or financial support or is there a difference?

No, the same process applies for proposals that request drug only, funding only, or both drug and funding.

Do I have to complete the entire application in one session, or can I come back to it later?

Yes, you are able to save your work and come back to it another time by clicking "Save Draft" at the bottom of the page. At any time prior to submitting, you will be able make changes to the application. However, once you submit your application, it will be locked from editing.

May I submit another proposal if I already have a funded study with BIPI?

Yes you may submit additional proposals, however, please note that any non-compliance in the ongoing study may preclude the review of new submissions until all issues are resolved.

Frequently Asked Questions-Review Process

How will BIPI communicate with me regarding the status of my application?

Email notifications will only be sent to the registered user account throughout the process. In addition, you may also log onto **Lectrona** to manage your proposals, view the status of your requests directly, and view any pending action items.

When should I expect a decision to be made on my application?

Submissions of synopses and full proposals are reviewed by the review committee on a rolling basis. Following the review of the initial submission, you may be asked to provide additional information or clarification before a decision is rendered. The committee evaluates proposals according to their scientific merit, alignment with BIPI areas of interest, and available funding. BIPI will issue a decision – either approval or denial – to the investigator using the contact information provided in the grant submission.

Does previous research support from BIPI guarantee future support?

No, each proposal is reviewed on an individual basis, according to scientific merit, alignment with our areas of interest, and available funding.

Can I reapply if my proposal is declined?

Yes, we welcome investigators to apply again with other novel study ideas.

Frequently Asked Questions-Budget and Contract

If my study is approved, what are the next steps?

If approved, a contract, including budget with payment milestones, is executed between the institution of the Sponsor-Investigator's institution and BIPI. Financial and/or drug support is contingent upon full execution of the contract by both parties.

What are the budget requirements?

The budget must reflect fair market value for all costs and show per patient, per procedure cost. BIPI will accept clinical and scientific personnel support line items necessary for the safe execution of the study, but cannot remunerate direct salary support for the Sponsor-Investigator.

The overhead rate is a maximum of 40% of the total direct study costs. Overhead will not be paid on indirect study costs. If your institution's overhead rate exceeds 40%, we will require a copy of the exemption letter.

The following budget items are not permitted within BIPI policy:

- Sponsor-Investigator salary
- Personnel support not associated with the research study
- Procedural costs that are reimbursable through standard of care treatment
- Site equipment
- Office supplies
- Capital or reusable equipment
- Overhead for indirect costs
- Any costs which have not been included in the approved budget

For ECRs, budgets will be further negotiated pending finalization of the collaborative protocol.

How is Fair Market Value (FMV) analysis performed?

Once the budget is submitted, the assigned contract manager will perform FMV review based on industry-wide cost data. Additional information or clarifications may be requested.

How long does it take to execute a contract?

Contract execution can vary widely depending on the complexity of the negotiations and the requirements of BIPI and the institution. Please take this into account when planning timelines of your study.

How are payments managed?

External Research payments will be managed per the fully executed agreement. It is the responsibility of the Sponsor-Investigator's Institution to provide documentation to BIPI of the completed milestones per the agreement.

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Frequently Asked Questions-Study Management

How is a study initiated?

A study start-up teleconference is conducted with the study team to discuss study expectations, safety requires, roles and responsibilities, and other study processes.

How are study updates communicated to BIPI?

For clinical studies, enrollment logs, as below, are requested.

RECRUITMENT	
Date of Update	
Screening	**Actual**
▪ Entered Screening (# started screening)	
▪ Dropped Screening (# of screen failures, withdrawals)	
▪ In Screening (# still in screening)	
Treatment	**Actual**
▪ Randomized (# enrolled)	
▪ Dropped Treatment total (A+B+C) (# withdrawn from study)	
A. Adverse Events (# withdrawn due to AE, including death)	
B. Treatment Failure (# withdrawn due to treatment failure)	
C. Other (# withdrawn due to another reason)	
▪ In Treatment (# still on treatment)	
▪ Completed Treatment (# completed treatment)	

How should study protocol changes be handled?

Study protocol changes must be submitted for BIPI review when there is change in the design and/or implementation of the study. This should occur prior to IRB submission. Please do not submit an amendment as a new research proposal.

What is the process for study closeout?

Once a study has been completed, a final study report must be submitted via **Lectrona**. All funds provided by BIPI in support of the study must be reconciled. Any unused product(s) that remain at the conclusion of the study must be destroyed per the Institution's policy with the written evidence of the destruction forwarded to BIPI. When the final study report has been reviewed and approved, a final invoice can be submitted for payment.

What are the expectations with regard to publishing external research study results?

Applicants receiving grants are expected to publish the results of their research. BIPI support of external research studies must be disclosed in any publication or presentation of the research. Any public presentation or disclosure of study results must be reviewed by BIPI prior to publication or presentation, as per the research agreement.