

Research Grants FAQs

Concept Application

What information is needed to apply?

All applications are required to submit the following;

- Investigator Contact Information, Medical License and signed CV (within the past 2 years)
- Study Concept Information (a full protocol is not required for concept review)
- Draft Budget, if requesting financial support

What if the Primary Investigator is not an MD or DO?

You will need to upload the Medical License of the individual providing medical oversight.

I am looking for a Letter of Support for my outside funding application (e.g. NIH). Do I still need to apply?

Yes, apply through the portal and then email research.grants@lantheus.com with your application number and request for Letter of Support review. Please note that LOS requests require 2 weeks for internal review.

What type of funding requests do you allow?

Lantheus can provide financial and free of charge study drug for marketed products.

Estimated budgets must include direct and indirect costs. If concept is approved, a full final line-item budget is required and must be within 10% of the estimated budget or application will be rejected and require a re-review.

When does Lantheus accept proposals?

We accept applications throughout the year on the application deadlines listed on <https://www.lantheus.com/responsibility/grants/>

If my Investigator Sponsored Trial is approved, what reporting is required?

Approved Trials must adhere to the following;

- Post study on www.clinicaltrials.gov
- Respond to all study update requests (progress reports, updated regulatory documents)
- Lantheus review of all abstract/manuscript publications up to 30 days prior to submission
- Uploading of de-identified PET/CT scans
- Reporting of Serious and Non-Serious Adverse Events
- Final report (publication)

How long does it take to review a proposal?

All proposals are assessed by Lantheus' Research Review Committee. Responses to applicants can take up to 12 weeks post application deadline. Please be aware that Lantheus CANNOT commit to review any research grant submission within a specific period.

When will I be contacted about the status of my proposal?

You can check the status of your proposal on your Cybergrants homepage. After an initial assessment, you may be contacted to provide additional information prior to Committee review. All communications will occur via e-mail or through our online grants program.

Can one investigator receive support for multiple grants?

Yes. Grant applications are based upon individual protocols; however, the committee does evaluate the capability of the investigator and research team to manage more than one research grant simultaneously.

Can my research coordinator submit my application/fill out the progress reports?

If an organization would like to designate a study coordinator to manage reporting requirements (study updates, amendment requests, etc.) on their behalf, scroll down to the bottom of the Welcome Page and follow the instructions for "Designating Study Coordinator(s)".

Protocol Application/Contracting

My Concept was approved now what?

Your application type will be switching from 'Concept' to 'Protocol' and you will be asked to start uploading required regulatory documents for Contracting and Onboarding. The required documents are;

- IRB Approved Protocol and Assent/Consent form
- IACUC Approval Letter (PreClinical Studies)
- FDA 1571/572
- IND Application/Letter (If applicable)
- Pharmacy Lab License/RAM License
- If requesting financial support
 - Full line-item budget
 - W-8BEN or W-9 Tax Documents
 - Bank Letterhead or Voided Check

How long does contracting take?

Contracting times vary depending on the duration the institution's review and the amount of markups given to the template. We aim to have a contract signed in 90 days post approval

Is an Agreement necessary?

Yes, an Agreement or contract is required prior to the initiation of any IST between Lantheus and your Institution. The Agreement outlines the terms for support as well as the responsibilities of the Investigator.

Mandatory disclosure under the Sunshine Act. Institution and Principal Investigator acknowledge that under Section 6002 of the Physician Payment Sunshine Provisions in the Affordable Care Act and commencing on August 1, 2013, Lantheus is required to report payments and other transfers of value provided to you for any purpose, including, but not limited to, the associated cost of vials of Study Drug provided, consulting, speaking engagements, advisory board services, travel, food, royalty payments, and clinical research.

Active Studies

How do I submit an invoice?

Once a milestone is reached, use your valid purchase order number and include the following on your invoice.

- Bill To: Must match the company within the Research Agreement
- Pylarify bills to: Progenics/Lantheus 201 Burlington Road, Bedford, MA 01730
- Invoice Number: Created by the vendor, each separate invoice requires a new invoice number
- Invoice must reference the contract, description, and reference project lead for the work
- Include details of the deliverables and total in USD

Send the invoice in PDF format to: apinvoices.us@lantheus.com and cc: Research.Grants@lantheus.com. Please Note Duplicate Invoices/Invoice Numbers can cause payment delays.

Queries on status of invoices can be sent to: ap@lantheus.com please note this is for questions only, **DO NOT SEND INVOICES** to this email.

Once this invoice is approved via our SAP system it will process according to the NET50 term from the date on the invoice once approved.

How do I report an Adverse Event?

Serious Adverse Events (SAEs) must be reported within one (1) business day of becoming aware of the event using the following contact information;

Pharmacovigilance
Agent Phone: 1-800-343-7851 or 1-978-667-9531
Fax: 1-978-436-7296
Email: lantheussafety@lantheus.com

Non-Serious Adverse Events (AEs) are reported as part of the study progress reports.

Should I list Lantheus as the Sponsor of my research?

No, Lantheus is not the Sponsor and should not be listed as such. Where appropriate, Lantheus can be listed as providing research grant support for the conduct of the study.

Whom should I contact if I have any questions?

Please e-mail your questions to Research.Grants@Lantheus.com and someone will reach out to you as quickly as possible.