LANTHEUS™

Investigator Sponsored Trial Application Form
Form MA_DIR_00238-FA (3.0)

Contact: Research.Grants@Lantheus.com
Phone: (800) 223-4051
Fax: (978) 436-7506

Internal use only
Clinical Grant Number: _____
Date Received: _____

Name of Grant Requestor: _____
Institution: _____
Address: _____
_____

Grant Check Payable to:
(if different from above): _____
Address to Send Grant Check: _____

Grant Amount: $US _____ Tax ID #: _____
(Enter N/A if request is for Drug Support only)

Contact Name: _____ Contact Phone: _____
Contact Email: _____ Contact Fax: _____

Product which is subject of study:

☐ **Cardiolite®** (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) Number of Doses: _____

☐ **DEFINITY®** Vial for (Perflutren Lipid Microsphere) Injectable Suspension Number of Vials: _____

☐ **Ablavar** (Gadofosveset Trisodium) Injection
Number of Vials: _____

☐ **Other** Specify: _____
Quantity: _____

Type of Application: ☐ Concept Proposal ☐ Detailed Protocol
Type of Study: ☐ Clinical ☐ Pre-Clinical (Animal/Lab)

Timeframe for execution of study: _____

Study Title: _____
_____

The Research Review Committee will evaluate each concept proposal/full protocol for:

- Scientific Merit/Medical Importance
- Investigator/Site Qualifications
- Approach/Methods
- Budget
- Appropriate Study Size
- Regulatory Requirements

Application must be accompanied by the following (see below for a description):

- ☐ **Letter of Request/Introduction**
- ☐ **Proposal or Protocol**

Where applicable, please also include:

- ☐ **Study Budget**
- ☐ **Signed and Dated CV**
- ☐ **Current Medical License**
- ☐ **IRB / Ethics Board / IACUC Approval**
- ☐ **Informed Consent**
- ☐ **FDA Form 1571 / 1572**
- ☐ **Investigator Training Documentation**

_____ _____
Signature of Grant Requestor: Date:

331 Treble Cove Road
N Billerica, MA 01862
www.lantheus.com

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At a minimum, you must provide the following:

☐ "**Letter of Request/Introduction**" that includes:

- ➢A summary of the study along with plans to collect, analyze, and prepare a report and publication of the results
- ➢Projected timing of study start in relation to IRB/Ethics Committee/IACUC review cycles
- ➢FDA or Health Authority requirements and plans to comply with regulations, as outlined in the FDA Form 1572
- ➢Institutional oversight and planned monitoring of the study
- ➢An overview of your research team
- ➢Funding sources
- ➢The "Letter" must be written on Department letterhead of the grant requestor and be signed by requestor

You may submit a concept proposal or detailed protocol for review:

☐ **Concept Proposal,** a short 2-4 page summary that includes:

- ➢Study Design
- ➢Objectives & Endpoints
- ➢Number of patients or animals to be studied
- ➢Inclusion & Exclusion criteria
- ➢Dosing & Imaging plans
- ➢Study procedures & plans to collect safety data

☐ **Detailed Protocol** must include all the items noted in the concept proposal above but in greater detail, at the level to submit for Institutional IRB/Ethics/IACUC review. A detailed protocol must also include:

- ➢Background/Introduction
- ➢Detail on study drug administration, planned dosing, total dose
- ➢Patient monitoring and SAE reporting
- ➢Statistical analysis plan to support the sample size calculation and endpoint analyses
- ➢Plans for study oversight and data monitoring

The following documents should accompany a detailed protocol:

- ➢Draft/Approved Informed Consent (IC) reflective of the study procedures and product risk/safety profile, as noted, in the package insert. Lantheus Medical Imaging should not be listed as the sponsor in the IC
- ➢If funding is requested, an itemized study budget
- ➢Signed and dated CV of principal investigator, current within 1 year
- ➢Copy of current Medical License, if applicable
- ➢Signed and dated FDA Form 1572, if applicable
- ➢Signed and dated FDA Form 1571, if applicable
- ➢Documentation of completion of your institution's investigator training

Important Points to Consider:

➢If the study is viewed favorably by the Committee, grant support is contingent upon execution of an Agreement.

➢Lantheus Medical Imaging is NOT the study Sponsor and should not be reflected as such in any document. If necessary, Lantheus may be identified as providing a research grant for the conduct of the study.

➢Responsibilities of the investigator include all SAE reporting, drug accountability, posting and maintaining study on clinicaltrials.gov and responding promptly to requests for study updates.

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