

# ESPERION

## Investigator Initiated Studies

An Ongoing Commitment to Investigator Initiated Studies

ESPERION believes in the need to support ethical independent research conducted by qualified third-party investigators. Such research must set out to address meaningful scientific and/or clinical hypotheses supported by valid study designs in which the privacy rights, safety and welfare of patients is the top priority.



## ESPERION INVESTIGATOR INITIATED STUDIES GRANTS SUPPORT

- ESPERION may provide financial support and/or study drug product for high quality scientific research that is initiated and conducted by outside Sponsor-Investigators, in accordance with the Policies and Procedures set forth herein.
- IIS Grants are intended to address unanswered scientific and medical questions, to advance the science, and enhance disease understanding and clinical outcomes.
- Grants for IIS may never be offered or provided as a reward or inducement to prescribe, purchase, use, or recommend ESPERION products.
- In order to avoid even the appearance that IIS Grants are awarded as an inducement to prescribe Company products or to encourage broader off-label use of a product commercially, it is essential that:
  - The purpose of the IIS is to answer a genuine scientific or clinical question that is consistent with ESPERION's research needs;
  - The IIS cannot be duplicative of other research that has been completed or is in progress;
  - The IIS cannot be a pretense to promote Company products;
  - The Sponsor-Investigator and affiliated institution must be qualified to conduct the intended research and have applicable experience, training and capacity
  - The Sponsor-Investigator and affiliated institution must adhere to the relevant patient safety and privacy laws.
  - The Sponsor-Investigator must document processes in place to ensure proper reporting of adverse events or product complaints.
  - The level of funding must be related to the fair market value for the research services and costs involved in conducting the IIS.



## AREAS OF STRATEGIC INTEREST



## GUIDE TO COMPLETING YOUR ONLINE GRANT APPLICATION

To access our online grant application, visit [www.esperion.com/science/grants](http://www.esperion.com/science/grants) to find the required information needed to submit an application.

Each section contains a detailed checklist of information required to complete an application including:

- Formal letter of request for funding
- Program brochure or agenda/list of topics
- Grant proposal
- Detailed budget



### Use of IIS Support

The Principal Investigator and Institution will use IIS Support solely for purposes of the Study for which it was provided. The IIS Support shall not be used by the Institution to pay the salary of the Principal Investigator or to purchase capital equipment. Examples of capital equipment include, but are not limited to, computers, cellular phones, tablets,

machinery, appliances, camera equipment, and sensors. IIS Support may be used for equipment rental if such equipment rental is included in the Institution-provided study budget. At the completion of each Study, Principal Investigator will confirm in writing that the IIS Support has been used only to support that Study by completing a Certification of Study Closure form provided by Esperion. For Studies that are prospective clinical trials, IIS funds may not be used to pay physicians for referring potential subjects for enrollment in the Study.

You will also find answers to frequently asked questions and the option to track the status of your grant application as it moves through the review process. We will only consider completed applications. Once your application has been submitted, you will receive an email confirmation and notification of any additional information required, if applicable.

## THE ESPERION INVESTIGATOR-INITIATED STUDIES REVIEW COMMITTEE

The ESPERION Investigator-Initiated Studies Review Committee will review your application to evaluate the following criteria:

- Medical/Scientific merit and feasibility of the IIS
- Strategic alignment of the IIS with ESPERION's therapeutic areas of focus, and its IIS strategic plans
- Sponsor-Investigator's qualifications, including his/her experience, training, and capability to perform all responsibilities as the Study Sponsor-Lead Investigator, such as filing for any necessary regulatory approvals (this also includes consideration of qualifications of study team and institution if this information is available)
- Prior experience of the Sponsor-Investigator in successfully conducting and completing clinical studies



The committee will also assess the alignment of your proposal with our areas of strategic educational interest. The committee also assesses whether a proposal meets overall review criteria. The Sponsor-Investigator (or Grant Requester) is required to submit a formal, electronic request for an IIS Grant directly to Medical Affairs via the IIS submission portal which can be found at [www.esperion.com/science/grants](http://www.esperion.com/science/grants). The electronic request for the IIS Grant should include, at a minimum:

1. A statement of the unanswered scientific or medical question to be addressed by the IIS;

2. Information about the Sponsor-Investigator and affiliated institution, sufficient to enable ESPERION to evaluate their respective qualifications (the Curriculum Vitae (CV) of the potential Sponsor-Investigator must be provided as well as information about the institution that will aid the committee in the decision-making process);
  - o A concept proposal and/or protocol synopsis;
  - o A proposed budget, with as much line-item detail as possible (budget should be annualized for all studies expected to be greater than 1 year in length); and
  - o Identification of the Institutional Review Board (IRB) or Ethics Committee (EC) to be used if the IIS is a clinical study.
  - o If the IIS is a clinical study, IRB/EC approval will be a pre-condition to receiving ESPERION funding.
3. ESPERION or the Sponsor-Investigator may request execution of a Confidentiality Disclosure Agreement (CDA) prior to IIS submission or at any time during the review process. Regardless of the presence or absence of a CDA, ESPERION colleagues must maintain confidentiality with regards to specific ideas submitted via the IIS process.

## DECISION AND NOTIFICATION

Initial Decisions by the IIS Committee Regarding the Concept Proposal Include:

1. Approved: the IIS Review Committee has approved the concept proposal and request a full concept proposal be provided via the grants portal.
2. More information required: (Medical Affairs obtains required information, which may include a request for the full study protocol and detailed budget.)
3. Denied: (IIS Coordinator issues a "Not Approved" letter to the Sponsor-Investigator)

Final Decisions by the IIS Committee Include:

- o Approved: (Proceed to developing IIS study agreement)
- o Denied: (IIS Coordinator issues a "Not Approved" letter to the Sponsor-Investigator)

### Process for Communicating Grant Decisions

Applicants will receive notification of final decisions via the IIS portal.

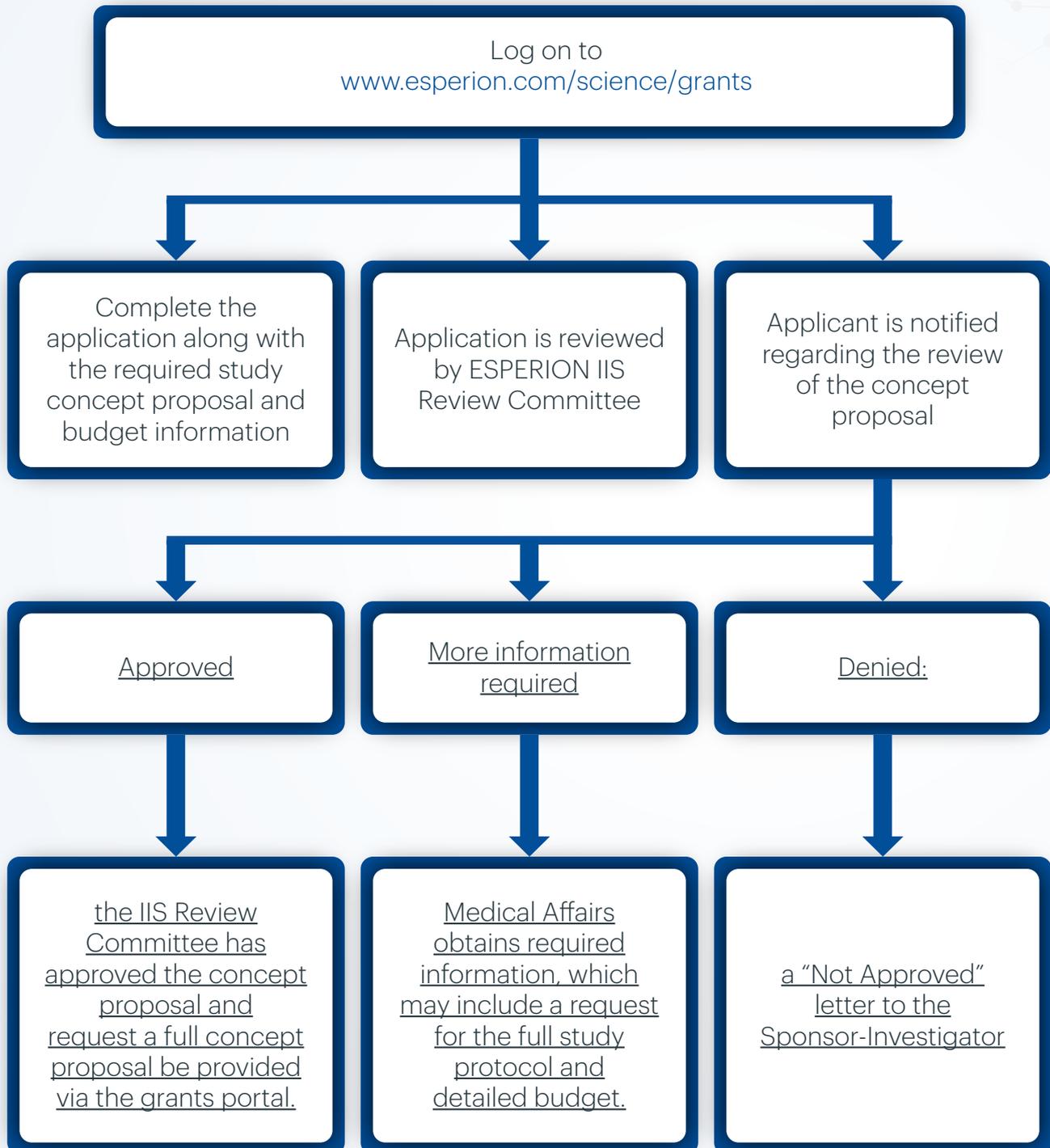


## Contractual Requirements and Process

### Contractual Requirements

- Sponsor-Investigator must agree to provide ESPERION with a copy of any final study results and any resulting publications for ESPERION's review at least 14 days prior to the planned submission.
- While ESPERION generally does not receive raw or patient-level data, if the Committee requests raw data or patient-level data for an IIS study, such requirement must be clearly documented in the Agreement.
- Intellectual Property (IP) or Patent Counsel must be consulted regarding rights to inventions and/or discoveries resulting from the IIS prior to the communication of a final decision to the Sponsor-Investigator and as well as prior to publication.
- ESPERION reserves the right to review proposed publications or other public disclosures of the results of the IIS prior to publication in order to prevent inadvertent disclosure of ESPERION's proprietary information, as well as the right to request a short delay in publication in order to protect such rights.
- The Sponsor-Investigator must agree to adhere to recognized ethical standards concerning publications and authorship, including the disclosure of ESPERION's financial (or study drug) support of the IIS in any publication of the study results. All relevant studies must be registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and the results must be reported.
- Whenever feasible, grant payments should be milestone-based. Preferably, initial payment should be pre-conditioned upon receiving IRB approval (in the case of clinical studies) and the final payment should be predicated on ESPERION receiving any deliverables (e.g., receipt of data or publication manuscripts) as documented in the IIS agreement.
- If it is determined by the Sponsor-Investigator that additional funds are needed to either complete the funded research, or due to a need to broaden the scope of the project, a formal request with the appropriate justification documentation must be submitted to the IIS review committee.
- ESPERION should also request the right to a budget reconciliation of the IIS funding, as well as any documentation related to the conduct of the IIS that would demonstrate the appropriate execution of the IIS as stated in the approved IIS submission.
- ESPERION reserves the right to terminate an IIS for reasonable cause (to include, but not limited to misconduct, futility or in the event of product withdrawal from the market). ESPERION is not allowed to terminate an IIS based on anticipated study outcomes.

## APPLICATION PROCESS AT A GLANCE



## | HOW TO CONTACT US: |



For more information or to submit an online grant application, visit [www.esperion.com/science/grants](http://www.esperion.com/science/grants)



If you have specific questions, please send an email inquiry to [grants@esperion.com](mailto:grants@esperion.com)