SUNOVION

SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Investigator-Initiated Studies Policy		POLICY NO: 1.14	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: December 16, 2011	Page: 1 of 9

1. PURPOSE:

This policy describes the procedures to be followed for initiating, documenting, responding to, and obtaining approval for requests for grants (funding and/or free product) for scientific and medical research that is sponsored by the investigator, and not by Sunovion Pharmaceuticals Inc. ("Sunovion"). The purpose of this policy is to ensure that Sunovion personnel comply with legal, regulatory and internal requirements for making research grants for studies designed, conducted and supervised by the clinical investigator (Investigator-Initiated Studies).

2. DEFINITIONS:

2.1 Adverse Event (AE): An unwanted effect associated with the administration of a drug. Onset may be sudden or develop over time.

2.2 Fair Market Value (FMV): The actual value of the service requested by Sunovion as determined by reference to a number of legitimate factors. Factors may include location of services, quality and difficulty of service, number of hours spent, comparable precedents and the individual(s) involved (skills, reputation, experience, etc.).

2.3 Informed Consent Form (ICF): A document that describes the rights of clinical study participants and includes details about the study, such as its purpose, duration, required procedures, and key contacts. The ICF also addresses the risk and potential benefits of participating in the study. After reviewing the ICF, the participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

2.4 Institutional Review Board (IRB): A committee of physicians, statisticians, researchers, community advocates, and others that ensure that a clinical trial is ethical and that the rights of the study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin.

Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, consult an IRB that

initially approves and periodically reviews the research in order to protect the rights of human participants.

2.5 Investigator-Initiated Study (IIS): A clinical study that is proposed by an investigator who acts as the Sponsor-Investigator of the trial and takes responsibility for the appropriate conducts of the study in accordance with all applicable laws.

2.6 Policy: This term references the Investigator-Initiated Studies Policy.

2.7 Sponsor: An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial as defined by local regulations.

2.8 Sponsor-Investigator: The obligations of a Sponsor-Investigator include both those of a sponsor and those of an investigator.

3. APPLICABILITY AND RESPONSIBILITIES:

This Policy applies to Sunovion Pharmaceuticals Inc. and its affiliates, where applicable.

3.1 Investigator-Initiated Study Coordinator

- 3.1.1 Receives and processes all requests for Investigator-Initiated Studies
- 3.1.2 Serves as Sunovion's single Point of Contact for communication with Requestors regarding the grant process from request through review, approval or denial.
- 3.1.3 Maintains documentation required by this policy to monitor IIS grant requests
- 3.1.4 Discloses IIS grants in accordance with federal and state law and Sunovion Policy 1.02

3.2 Scientific Review Committee

- 3.2.1 Evaluates and approves or denies IIS grants requests in accordance with this Policy
- 3.2.2 Includes a Medical Affairs Liaison (from appropriate therapeutic team) and representatives from Clinical Operations, Medical Affairs, Law, and Compliance. Sales and Marketing personnel may not serve on the Scientific Review Committee.

3.3 Medical Affairs Liaison - Scientific Review Committee Ad Hoc Member (non-voting)

3.3.1 Conducts initial evaluation of the proposed study's scientific integrity and consistency with appropriate medical or scientific needs.

3.3.2 Responsible for providing comments to and obtaining additional information from Sponsor-Investigator

3.3.3 Conducts capabilities assessment of the Sponsor-Investigator

3.3.4 Informs Sponsor-Investigator of decision by Scientific Review Committee's

3.3.5 Obtains IIS contract from the Law Department

3.4 Clinical Operations Representative - Scientific Review Committee Member

3.4.1 Serves as Sunovion's Point of Contact with the Sponsor-Investigator regarding ongoing approved research grants.

3.5 Medical Affairs Representative - Scientific Review Committee Member

3.5.1 Chairs Committee and provides medical evaluation of the proposed study, including a review of study purpose, protocol, endpoints and inclusion and exclusion criteria to ensure scientific rigor and consistency with the strategic medical plan.

3.6 Legal Representative - Scientific Review Committee Member (non-voting)

3.6.1 Conducts a legal evaluation of the proposed study, including a review of the study with respect to applicable state and federal laws.

3.7 Compliance Representative - Scientific Review Committee Member (non-voting)

3.7.1 Conducts a compliance evaluation of the proposed study, including a review of the study with respect to Sunovion applicable policies and procedures.

4. GENERAL:

4.1 Studies Eligible for Support

All Investigator-Initiated Studies must be legitimate, address an unmet scientific or medical need, and be consistent with the strategic medical plan. With this in mind, Sunovion may support the following kinds of Investigator-Initiated Studies:

- Investigational New Drug Application (IND) and Non-IND studies;
- Drug Utilization Evaluations, pharmacoeconomics, in-vivo/in-vitro, animal studies and retrospective studies;1
- Clinical studies of unapproved uses involving approved or unapproved Sunovion products;

1 In cases where the NDA is filed but not yet approved, the study will be conducted under an IND that is cross referenced to the Sunovion IND.

- Observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease;
- Other types of independent research on disease states, including novel diagnostic screening tools and surveys where Sunovion has no direct commercial interest.

4.2 Studies Not Eligible For Support

Sunovion will not support studies that are designed to generate business for Sunovion, nor will we support studies where off-label uses of our products are being promoted. In addition, Sunovion will not support the following:

- Requests for support for ongoing or new research without an associated study protocol or synopsis;
- General education and training activities;
- Support for ongoing clinical programs that are part of an organization's routine operations;
- Start-up funds to establish new clinical or research programs or to expand existing programs;
- Purchases of capital equipment unrelated to the study or that would generate revenue;
- Construction funds to build new facilities; or

  - Hiring of staff that are not dedicated to the study.

In addition, Sunovion will not enter into an Investigator-Initiated Study arrangement for the purposes of:

- Generating federal healthcare business (e.g., purchasers, benefit managers, formulary committee members, group purchasing organizations, physicians and certain HCPs and pharmacists);
- Directly or indirectly inducing or rewarding the referral or recommendation of business (e.g., product purchase, prescriptions, formulary placement);
- Interfering with or skewing clinical decision-making;
- Increasing costs to federal healthcare programs, beneficiaries, or enrollees; or
- Increasing risk of overutilization or inappropriate use of our products.

4.3 Submissions

Investigator-Initiated Studies must be initiated by the investigator and should not be solicited or initiated by Sunovion. Sponsor-Investigators must submit research grant requests to Sunovion's IIS Coordinator in writing. Requests may be submitted as either a Concept Submission or a Full Submission, as discussed in more detail in section 7.1. If Sunovion is interested in the Concept Submission, Sunovion will issue a follow-up request for a Full Submission.

4.4 Appropriate Grant Recipients

Sunovion may only award IIS grants to applicants based on their professional qualifications, expertise in the relevant therapeutic area, experience with conducting clinical trials and complying with applicable regulatory obligations of a clinical trial sponsor, and available resources including facilities and support staff. Under no circumstances should the Sponsor-Investigator's prescribing history or relationship with Sunovion be considered in decisions to fund IIS grant requests.

4.5 Independence of Sponsor-Investigator

The Sponsor-Investigator must retain full and final discretion and responsibility for all aspects of the study design, implementation, data analysis, and data publication and dissemination. Sunovion personnel may not draft the study protocol, case report forms, regulatory submissions, or other study documentation, and may not direct decisions related to study design, provision of medical care to study participants, adverse events or other aspects of trial implementation or analysis.

4.6 Financial and Product Support

4.6.1 Sunovion may provide financial support to Investigator-Initiated Studies that meet its criteria and are approved by the Scientific Review Committee. Sunovion will conduct a fair market value assessment to determine the appropriate funding for a particular study. Sunovion will utilize established objective criteria to determine the fair-market value for the cost of each study.

4.6.2 Sunovion study drug must be provided free of charge by Sunovion for all studies. For Non-IND studies, where no drug is requested from Sunovion, the grant request must be reviewed by the Law Department Sunovion study drug must be properly labeled free commercial product or investigational product. Once product support has been approved by the Scientific Review Committee, Sunovion shall oversee the allocation and shipment of product support by:

- Determining the Sponsor-Investigator's product needs and timeline requirements
- Ensuring that the study drug to be provided is properly labeled;
- Tracking and documenting all study drug requested and provided;
- Verifying the site shipping address and contact name for initial and re-supply of study drug; and
- Ensuring that a completed and signed receipt confirmation is received from the Sponsor-Investigator following each shipment of study drug.

4.7 Sponsor-Investigator Responsibilities

The Sponsor-Investigator must sign a contract specifying, at a minimum, that the Sponsor-Investigator:

- Assumes all legal and regulatory responsibility for the conduct of the research;

- Agrees to comply with all applicable laws and regulations, including the ICH GCP Guidelines, HIPAA and other privacy laws;
- Maintains all required licenses and is not on any debarred, disqualified or restricted lists;
- Will obtain IRB approval of the protocol and informed consent form (ICF) and provide Sunovion with evidence of that approval;
- Will have control over publication and presentation of study data and will confirm that there is no proprietary information.
- Will disclose Sunovion's support of the study in any study publications or presentations.
- Will register the study and report study results on clinicaltrials.gov;
- Will not seek reimbursement for any study drug provided by Sunovion; and
- Has primary responsibility to report adverse events to regulatory authorities in accordance with applicable regulations, and, for marketed product, must provide Sunovion reports of drug-related deaths, serious adverse events, and other significant safety information in an expedited time frame.

In addition, the Sponsor-Investigator must disclose to Sunovion the extent to which any or all of the investigator's income is paid by the government.

4.8 Sunovion Responsibilities

With respect to IIS requests, Sunovion is required to:

- Ensure that investigators participating in the Investigator-Initiated Studies are not included on any government debarment, restricted, or "watch" lists;
- Ensure that the provision of funding for an Investigator-Initiated Study is in accordance with fair market value.
- Ensure that the funding for an Investigator-Initiated Study is not provided as an inducement or reward for recommending, prescribing, or purchasing Sunovion products.

4.9 Sunovion Deliverables

At the conclusion of the study, Sunovion shall be entitled to the following:

- Delivery of a limited data set;
- License to use the data generated by the study for any legitimate business purpose;
- Ownership of intellectual property generated during the course of the study

4.10 Study Maintenance

Sponsor-Investigators are required to update Sunovion periodically, as specified in the IIS agreement with the Sponsor-Investigator. Updates should include expenditures against budget and information related to enrollment, projected

publications, and projected completion dates. Sunovion also requires notification of any amendment to the original protocol after the research has begun.

4.11 Study Closure and Certification

Sponsor-Investigators are contractually required to provide Sunovion with final study results. Study results can be submitted in various forms, such as posters, manuscripts, reports, or detailed summaries. Any planned publication must be sent to Sunovion in advance of the publication, in accordance with the IIS Agreement.

Sponsor-Investigators must conduct an accounting of any Sunovion product provided for the study and return any unused product at the completion of the study.

At the closure of the study, the Sponsor-Investigator will be required to certify that the study was conducted and that the Sunovion funds or pharmaceutical products were used solely to conduct the study in question. The Sponsor-Investigator must also certify that all safety requirements were met.

4.12 Transparency and Publication

Sunovion supports the exercise of academic freedom and encourages Sponsor-Investigators to publish the results of the study, regardless of whether or not the results are favorable to Sunovion. The Sponsor-Investigator must comply with recognized ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, www.icmje.org established by the International Committee of Medical Journal Editors.

4.13 Procedure

IIS Requests/Submissions

Sponsor-Investigator seeking funding or free product to support a study shall submit a signed letter of request on the Sponsor-Investigator's organizational letterhead containing the information required for a Concept Submission or a Full Submission, as appropriate, in accordance with Sunovion SOP on Grants for Investigator-Initiated Research (IIS Studies).

4.14 Review and Approval or Denial of IIS Grants

Sunovion's Scientific Review Committee reviews and approves or denies all IIS grant applications in accordance with the following review criteria:

- Scientific merit of the proposed study and study design;
- Alignment of proposed study with predetermined areas of therapeutic interest;
- Expertise of the investigators, including ability to perform the study in accordance with applicable regulatory, industry, and ethical guidelines and ethical standards;
- Reasonableness of proposed budget;

- Whether any grant funding provided is in accordance with fair market value;
- Whether the grant rewards or appears to reward past prescription, purchase, or referral behavior for any Sunovion product;
- Whether the grant induces or appears to induce future prescription, purchase, referral, formulary placement behavior for any Sunovion product; and
- Whether Sunovion personnel have attempted to influence the content of the research.

All IIS grant requestors shall be checked against the FDA, OIG, and GSA federal healthcare programs exclusion or debarments lists. IIS Grants may not be awarded to any organizations that appear on such lists. Sponsor-Investigator(s) shall be checked to determine whether there have been any changes in the status of his/her medical license due to disciplinary action taken by a state medical board.

The IIS Coordinator is responsible for notifying the organization making the request for a research grant when the request is approved or denied.

4.15 IIS Grants Disbursement Process

When a grant is approved, the chair of the Scientific Review Committee or designee will indicate approval in the meeting minutes or other documentation. Upon execution of a research grant agreement, disbursements will be made in accordance with the payment schedule set forth in the grant agreement.

4.16 Documentation

The IIS Coordinator will maintain a tracking system to monitor grant requests and payment history.

Documentation to be maintained for grant requests shall include:

- Grant application or request letter;
- A budget with a breakdown of expenses to be covered prepared by the requestor;
- Documentation confirming that the funding is for a bona fide scientific or medical research purpose;
- Documentation confirming that the grant will be provided directly to the organization and not to an individual healthcare professional; and
- Documentation confirming that the grant will be used for the intended research.

5. OTHER MATTERS

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, "**Corporate Policy Review Committee**."

5.2 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES MAY BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

5.3 Reporting Concerns

Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sunovion's Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

(a) Toll free telephone number. 866-886-1348
(b) Via the internet at: www.ethicspoint.com

Sunovion does not tolerate any form of retaliation or adverse action against any employee who submits a report of misconduct. In addition to these protections, an employee may also avail themselves of the remedies afforded under federal and state law, including the federal "False Claims Act," 31 U.S.C. Sections 3729-3733, the Commonwealth of Massachusetts Whistleblower Protection Act, M.G.L 149, Chapter 185 and the New Jersey Conscientious Employee Protection Act, N.J. Stat. Ann. Section 34:19, Sections 1 to 8.

5.4 Audit

Each department; shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

5.5 Cross-References to other Corporate Policies

- Code of Conduct and Ethics
- Adverse Events Policy
- Conflicts of Interest Policy