SUNOVION

SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

TITLE: Sunovion Clinical Studies Policy		POLICY NO: 9.0	
Supersedes: Policy No. 9.51	Approval Signature: Corporate Policy Review Committee (CPRC)	Date Issued: March 1, 2011 Date Amended: June 22, 2011	Page: 1 of 4

Section 1. PURPOSE:

The purpose of this policy is to set forth the Sunovion Pharmaceuticals Inc ("Sunovion") standard for the conduct of clinical studies/trials. Sunovion strives to maintain high ethical, scientific, and clinical standards in all studies regardless of where these studies are conducted. Sunovion studies are designed and conducted in accordance with local laws and generally accepted international regulatory standards. This policy is meant to ensure that Sunovion Studies respect the rights of all study participants.

Section 2. DEFINITIONS:

"Contract Research Organization (CRO)" means an entity engaged in the business of providing clinical development services to pharmaceutical companies for the development of experimental new drugs and marketed drugs.

"Sunovion Studies" means any study of a Sunovion drug product conducted by or on behalf of Sunovion where Sunovion or its affiliate is the Investigational New Drug Application (or foreign equivalent) holder. Refer to the Investigator Initiated Studies Policy for more information about Investigator Initiated Studies.

Section 3. APPLICABILITY:

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

The scope of this policy applies to all Sunovion Studies, including those conducted in countries that do not have an established human protection infrastructure, and includes single site studies, multi-site studies and multinational studies. It also applies to parties with which Sunovion enters into contracts (e.g., Contract Research Organizations or consultants) who are involved in Sunovion Studies.

Section 4. CONDUCT OF CLINICAL TRIALS:

4.1.1 Compliance with Local and International Norms. Sunovion Studies are to be conducted in accordance with accepted ethical, scientific, and clinical standards. Specifically Sunovion takes measures to ensure that all Sunovion Studies are conducted in accordance with local laws and regulations, as well as with well-accepted international standards for clinical research, including standards published under the International Conference on Harmonization (ICH), PhRMA principles, and other standards associated with Good Clinical Practice (GCP).

4.1.2 Appropriateness. Sunovion Studies are designed to answer clearly defined questions and must be relevant to the host country's health needs.

4.1.3 Ethical Review. In order to ensure appropriate ethical standards are observed, Sunovion Studies must be reviewed by a qualified Institutional Review Board (IRB) or Independent Ethics Committee (IEC).

4.1.4 Informed Consent. Sunovion Studies must conform to ICH and GCP standards for informed consent. Sunovion also follows local laws and customs, as appropriate. All study participants or legal guardians must provide voluntary informed consent after receiving information about the risk of participation, study design, and potential benefit prior to participating in a Sunovion Study.

4.1.5 Standard of Care for Control Groups and Use of Placebos. The standard of care provided to control groups should be, at a minimum, equivalent to well-established and commonly employed local treatments. Placebo-controlled studies are permitted where doing so does not present undue risk to the health or well-being of the study participant and in all cases undergo IRB/IEC review.

4.1.6 Safety Oversight. For Sunovion Studies, regulatory agencies and IRBs/IECs, as applicable, are informed of potential new risks associated with the use of a product. Research participants must be informed of potential new risks associated with use of a product as well as any additional monitoring or follow-up testing that will be conducted following completion of a study

4.1.7 Privacy. Sunovion is committed to complying with applicable laws addressing the privacy of clinical research participants and will require that its agents are contractually obligated to do the same.

4.1.8 Clinical Trial Disclosure. Sunovion discloses information on applicable clinical trials as required by US state and federal law, international laws, and PhRMA principles. Sunovion is committed to ensuring public access to applicable clinical trials through disclosing information on public portal(s), and potentially other communication methods, including but not limited to, publishing in medical journals, and communicating at medical conferences. Sunovion is committed to timely communication of results, positive and negative, from applicable clinical trials in accordance with U.S. state and federal law, international laws, and PhRMA principles.

Section 5. AMENDMENT

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 (CPRC)**."

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 the Sunovion Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior are 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 good faith. 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.

Section 6. RELEVANT POLICIES AND DOCUMENTS

Code of Conduct and Ethics

Anti-Corruption Policy

External Communication Policy

Business Travel Policy

Conflict of Interests Policy

Any and all applicable SOPs

PhRMA Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results (April 2009)

PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, as revised January 2004 and January 2009)