

## **Clinical Trials Policy**

### ***Presented for Adoption November 20, 2013***

#### Preliminary Information

Clinical research trials are conducted by pharmaceutical and medical device companies to collect data regarding the safety and efficacy of new drugs and medical devices. Clinical trials are integral to innovation in the life sciences. A multitude of innovative therapies are generated in laboratories, but few survive early development to reach the point of human testing. Clinical trials in patients suffering from a specific condition provide a crucial link between scientific discovery and medical utility. The planning and execution of a clinical trial can take years and can cost hundreds of millions of dollars. Because of the potential risk posed to subjects and consumers by clinical trials of drugs and medical devices, human research is highly regulated by the U.S. Food & Drug Administration and other federal agencies.

Patient recruitment is a major challenge for clinical trial sponsors. Patient enrollment is the most time consuming aspect of the clinical trial process, taking up to 30 percent of the clinical timeline. Expensive delays in product approval may result if recruitment problems arise. As the number of patients needed for clinical trials rises, the demand for patient recruitment services has increased. The liability exposure associated with clinical trials has increased as well.

A diverse group of stakeholders involved in clinical research trials (including sponsors, research investigators, physicians, regulators and patient advocates) must recognize the legal and ethical responsibilities owed to participants and must ensure that clinical study protocols are developed and implemented in accordance with government regulations and established industry best practices.

#### Policy

The National Eczema Association (NEA) is fully supportive of all aspects of the clinical research trial process in connection with the development of products and therapies related to eczema treatment and prevention. After careful consideration of the responsibilities required by clinical research trials and NEA's current human and financial resources, NEA has determined that adherence to the following principles will best enable it to further its mission and fulfill its obligations to its constituency relative to clinical research trials:

1. NEA shall not endorse, sponsor or conduct clinical research trials.
2. NEA shall not recruit participants for clinical research trials.
3. NEA may provide full or partial funding for eczema related clinical research trials at such time(s) and in such amount(s) as may hereafter be determined by the NEA Board of Directors to be in furtherance of NEA's mission and compatible with NEA's human and financial resources.
4. NEA shall make every reasonable effort to inform its constituents regarding eczema related clinical research trial availability and participation, whether upon request of the sponsor or investigator or upon its own initiative.
5. All notifications issued by NEA regarding clinical research trial availability and participation shall be accompanied by a disclaimer in substantially the following form:

#### Disclaimer

The National Eczema Association (NEA) is committed to improving patients' quality of life through research, education, and support. NEA does not provide medical advice to patients but provides information to help them better understand their health, diagnosed conditions and the current range of approaches related to eczema treatment, prevention and supportive care. NEA urges patients to consult with a qualified physician for diagnosis and treatment.

As part of the fulfillment of its mission, NEA provides information to its constituents regarding clinical research trial availability and participation. NEA does not recruit patients for clinical trials and NEA does not conduct clinical trials. Below is a notice for a research study that we thought might be of interest to you. NEA is providing this information as a service. NEA does not endorse the study, which is being conducted at locations and under protocols that are not monitored or reviewed by NEA. Accordingly, NEA cannot be held responsible for anything that may occur in connection with the study. NEA may be reimbursed by the sponsor of the study for costs incurred in connection with notifying NEA constituents of the availability of the study. Should you have any questions regarding the study, please contact the study sponsor.

NEA respects your privacy and does not release your private information to any outside individuals, companies or organizations.

6. NEA may request and/or obtain reimbursement from clinical research trial sponsors or investigators for all costs incurred by NEA in connection with notifications to constituents regarding eczema related clinical research trial availability and participation.