



Supporting you. Supporting each other.

NATIONAL FOUNDATION FOR
ECTODERMAL DYSPLASIAS

Conflict Of Interest; Corporate Relationship Guidelines

Conflict of Interest

Volunteers and staff of the NFED contribute to the mission of the organization in various ways. They participate on the Board of Directors, Scientific Advisory Council, Patient Care Council, Family Support Council, and deal with issues that have far-reaching implications. The Foundation is well served by the fact that many of those involved have diverse interests and are involved in a number of activities outside the Foundation. This interest and involvement enhances the expertise these individuals bring to the various roles they fill in representing the Foundation.

On occasion, however, situations arise in which an individual serving the Foundation in an elected or appointed position, or as a staff member, has a conflict of interest that may be, or could be perceived as a relevant duality of interest or even a conflict of interest. Generally, a relevant conflict of interest could be said to exist when individuals have material interests outside the Foundation that could influence them or could be perceived as influencing them to act contrary to the interests of the Foundation and for their own personal benefit or that of a family member or a business associate. Most often, a relevant conflict of interest is financial, such as when an individual has an employment relationship, a stock ownership interest, or a consultative or advisory arrangement, or receives a grant or stipend. In some situations a conflict of interest may exist even though the conflict does not arise out of financial considerations.

In addition, health-care professionals frequently contribute to the scientific and medical programs and activities sponsored by the Foundation. Such contributions may be made with support from the biomedical industry. Guidelines from the Accreditation Council for Continuing Medical Education (the continuing medical education certification body that authorizes the provision of CME credits) specifies that all contributors must disclose to the sponsoring body their relationship with the biomedical industry. Thus, it is now mandatory that participants in CME events disclose all relevant dualities of interest. In addition, a similar practice is now in effect between authors and the journals and publications to which they contribute papers.

A key element in monitoring relevant conflicts of interest and in avoiding potential conflicts is a system in which those serving the Foundation provide disclosure of their interests. By disclosing such interests to the Foundation, the Foundation can determine if a duality of interest is relevant and can determine the steps that should be taken to minimize the likelihood that a conflict would arise.

It is not the intent of this policy to prohibit or discourage anyone from participation in the activities of the Foundation. Closely related conflicts of interest are not inherently wrong or bad, but the Foundation must be made aware of such interests

in order to be able to evaluate fully their impact on the mission and activities of the Foundation.

The following categories of volunteers and staff are required to annually disclose to the Foundation any conflicts of interest that may be relevant to the work of the Foundation:

- Members of the Board of Directors;
- Members of Family Support Council
- Members Patient Care Council
- Members of the Scientific Advisory Council;
- Staff;
- Liaisons
- All authors, editors, and editorial board members of NFED publications;
- All speakers/presenters in continuing medical education events, including presenters of original scientific research;
- Other members of committees and task forces whose work focuses on scientific/medical issues which are of interest to the biomedical industry.

Reviewers of manuscripts need not make a formal disclosure of their relevant dualities of interest. However, reviewers are encouraged to disqualify themselves from reviewing any manuscript that deals with a matter in which they or an immediate family member has a direct interest.

The following relationships must be disclosed to the Foundation:

- Employment. The name and nature of all employers must be disclosed.
- Membership on the Board of Directors or any fiduciary relationship with another organization.
- Membership on a scientific advisory panel or other standing scientific/medical committees of another organization.
- Stock ownership. Shares of stock directly owned or controlled, including those owned or controlled by an immediate family member.
- All consultative or advisory arrangements for which monetary compensation is received.
- Grants/research support. Grants or research support from a company/organization whose products or services are directly related to the subject matter in a manuscript or presentation.
- Honoraria.

If relevant conflicts exist for immediate family members they, too, should be disclosed.

It is obvious that all categories, conditions, or circumstances that should be disclosed cannot be listed. A reasonable test to guide decisions about what to disclose is to ask whether any particular affiliation or interest could cause embarrassment to the NFED, or to the individual or institution involved, or lead to questions about an individual's motives, if such affiliation or interest were made known.

Those individuals affected by this policy must complete a Conflict of Interest Disclosure Statement (Attachment B) at the time they are appointed or elected to a new term or become officially associated with an activity of the Foundation. Thereafter, a new Statement must be completed annually. Members of the staff required to complete the form will do so annually. Additionally, those completing a Statement are expected to notify the Foundation in writing if there are any material changes since the last form was completed. All completed statements will be kept strictly confidential.

The Audit, Budget, and Finance Committee is to develop, approve, and evaluate the Disclosure Statement(s) used by the Foundation; to review the reporting and disclosure process to ensure that it is consistent with the purpose of this policy; to make regular reports to the Board of Directors to affirm that all members of the Board and senior staff have completed Disclosure Statements; to review, approve, and monitor the process and method by which there is disclosure of relevant dualities of interest in publications and programs; to provide recommendations or instructions to individuals completing a Disclosure Statement regarding actions that should or must be taken to reduce or eliminate a potential or real conflict; and to review this policy and make recommendations for revision whenever appropriate.

In any matter coming before the Board of Directors, Scientific Advisory Council, Patient Care Council, committees, or a task force in which an individual has a relevant duality of interest or a real conflict occurs, the individual affected shall leave the room in which the meeting is being held and refrain from any discussions or actions on that subject. In most situations, no further action will be required. However, in some instances, the nature of the situation may require other actions be taken. The minutes of the meeting will reflect abstentions from voting due to these circumstances.

In the case of scientific/medical presentations or publications, those individuals with a relevant duality of interest will be identified in the program or publication. (Attachment B)

Guiding Principles for Corporate Relationships

It is important that the NFED be consistent with its relationships with for-profit businesses or corporations. For the purposes of the standards below, it is assumed that the partnering business has an outstanding reputation, is known for the quality of its products and that the relationship can begin or end at the behest of the NFED's Board of Directors. In all cases any contracts or agreements will be submitted to legal counsel for review and to the Board of Directors, Scientific Advisory Council and/or the Patient Care Council for approval. In some situations, i.e. funding for special events, the Board of Directors will be apprised of the relationship prior to the event. The Board of Directors will evaluate on an annual basis the total amount of corporate support received as a percentage of total revenue.

The NFED exercises the right of independent judgment in all its decision making regarding any corporate relationship. There must always be a meaningful mission related benefit to our constituents and any relationship must be consistent with the NFED's principles, policies, values and standards. All relationships must adhere to all

local, state and federal laws. Any information shared with the public must contain accurate and non-deceptive terms or statements which can be easily understood.

Written agreements between the NFED and any for-profit business or corporation must include the amount of money to be transferred to us, whether any restrictions are associated with the gift, the mission-driven activity involved, the content of any disclosures to the public, agreement that the NFED retains complete control over information related to the event and details of how our logo or other identifying marks may be used. The NFED will not enter into agreements in which comparisons among competing products are being made.

Program Sponsorships:

The NFED is happy to partner with businesses that share our commitment to individuals affected by ectodermal dysplasia. While sponsorships will be acknowledged with appropriate signage or reference, they will not dictate program content. In the case of professional medical education, all programs will be conducted in accordance with the guidelines of the Accreditation Council for Continuing Medical Education. Similarly, dental programs will be conducted in accordance with the guidelines of the American Dental Association Continuing Education Recognition Program.

Event Sponsorships:

Having financial support for our various activities enables the NFED to use our funding for sustaining direct services to our families. Sponsors must share our commitment to individuals affected by ectodermal dysplasias, must be well respected, and must not expect anything in return. Such sponsorships are acknowledged through signage or other reasonable reference.

Health Message Promotion:

The NFED must have control over the content of all messages. Use of the organization's name, logo or message will be determined on a case by case basis.

Strategic Alliance or Partnership:

The NFED will work jointly with a company when mutual interests of both parties are well-served, when the outcome is in the best interest of our constituents and after all plans and activities receive approval from the Board of Directors. The NFED will not partner with any business whose mission is in conflict with that of the NFED.

Consumer Product Purchase:

Fundraising opportunities for profit sharing related to point of purchase products will be investigated and encouraged as long as the product has a bearing on care necessitated by the effects of ectodermal dysplasia and an awareness opportunity is created. The amount or percentage of money to be directed to the NFED, the duration of the campaign, and any maximum or guaranteed minimum contribution must be disclosed to the public.

Endorsement:

The NFED will only consider endorsing products directly associated with the effects of ectodermal dysplasia that are sold over the counter. When applicable the product must have the approval of the U.S. Food and Drug Administration and must have proven to be outstanding in its effectiveness. Endorsements will specify whether they address a feature or attribute of the product or its overall efficacy. Such agreements will only be entered into following careful scrutiny and consideration.

Privacy:

At no time will personal information relative to constituents, donors, volunteers or others in touch with the NFED be given to any corporation without the expressed consent of the individual in question.

Yearly financial reports will include the amounts received from each corporation and their percentage as compared to that of total revenue. The reports will also include the total amount of all corporate support received. This disclosure will be made within six months of the close of the fiscal year in internal documents, on Form 990 and on the NFED's Web site where corporate contributions can be listed in ranges, i.e. \$10,000-\$20,000.

All new corporate relationships must be reviewed and approved by the Board of Directors prior to commencement. Ongoing relationships will be reviewed on an annual basis by the Executive Committee with a report issued to the Board of Directors. Any changes in the relationship must be reported to the Board of Directors within 30 days.

NFED Liability Mitigation – Special Events

In order to minimize liability arising from special events, the NFED will (a) inform its members and volunteers to take prudent precautions, (b) obtain waivers from participants where applicable, (c) rely on insurance from the facility hosting the event, and (d) obtain event coverage where applicable. Our goal in all situations is to take appropriate and diligent actions to mitigate risks, and act without negligence or recklessness. The NFED annually renews state registrations to assure that we are in accordance with applicable law. The Foundation will communicate with families or event sponsors that fundraising events must comply with all local, state and federal laws.

The NFED differentiates between NFED sponsored events and Family Fundraising Events events, based on the level of engagement and responsibilities of the NFED staff and how expenses are covered, in determining the necessary action.

NFED Sponsored Events

- Such events include National and Regional Family Conferences, professional and scientific symposia that may include member participation, and special fundraising events (e.g. Halloween Bash and Apple Golf Classic Tournament).
- The facility hosting the event must provide evidence of possession of liability insurance.
- Where child-care is necessary, the NFED will hire an external child-care provider to mitigate risks.
- Corporate sponsorship for an event may require the need to obtain specific coverage to meet their requirements.

Family Fundraising Events

- Such events include family gatherings (e.g. local picnics), and family managed special fundraising events sponsored by families or third parties (individuals or organizations other than the NFED and its staff).
- The fundraising events may vary from annual events (e.g. golf or skating) to one-time events, the number of participants involved, funds raised, and the type of events.

- In all situations the NFED will communicate to the volunteers the requirement to comply with all local safety rules and regulations and insurance requirements.
- All donations at family sponsored events are to be made in the name of the NFED.

On an annual basis the NFED will review all of its liability guidelines to assure due diligence. This will include:

- Review communications regarding education and safety precautions provided regarding all events, including any disclaimers.
- Review waiver forms used at various events. Review insurance from the facility hosting the event.
- Review of liability insurance for specific NFED sponsored events to assure adequate coverage for the events being held.
- Review industry best practices to assure our policies are consistent with industry norms.