

## **PULMONARY FIBROSIS FOUNDATION CONFLICT OF INTEREST POLICY AND PROCESS**

1. **Scope.** The following statement of policy applies to each member (employees including Staff Medical Advisors), the Board of Directors, Medical Advisory Board (MAB), Research Advisory Forum (RAF), Scientific Advisory Committee (SAC), other committee members, Ambassadors and Support Group Leaders, of the Pulmonary Fibrosis Foundation (the “Foundation”). The guiding principle surrounding possible conflicts of interest will be to always disclose, consistently manage the adjudication process on a case-by-case basis, and only sometimes prohibit activities to protect the PFF.
2. **Fiduciary Responsibilities.** Members of the Foundation have a duty of loyalty and duty of care, to serve the public trust and have an obligation to fulfill their responsibilities in a manner consistent with this fact.

All member decisions must be made solely on the basis of an unquestioned desire to promote the best interests of the Foundation and the public good independent of potential conflicts of interest.

The Foundation’s integrity and reputation must be also protected and advanced at all times. The Foundation recognizes that members of the team could have potential conflicts of interest that could be perceived as materially impacting the Foundation’s integrity and reputation, and its ability to serve the public good. It is also recognized that the Board of Directors, MAB members, Research Advisory Forum members, and medical advisors often have legitimate outside activities, which add value to the PFF.

It is everyone’s responsibility to ensure that the Foundation is made aware of situations of potential conflict. Potential conflicts of interest involve personal or familial (spouse, domestic partner, immediate family) interactions in:

- Business relationships
- Commercial Interests
- Institutional relationships
- Competing interests, including competing research or grants

Real or perceived conflicts in these areas could influence independent decision-making or compromise one’s ability to act in the best interest.

Thus, the Foundation’s Board of Directors annually requires each member of the Foundation to:

- a) Receive a copy of the Policy;
- b) Read and understand the Policy; and
- c) Understand that the Foundation is a charitable organization and that in order to maintain its tax-exempt status, it must exclusively engage in activities, which are directed towards the accomplishment of one or more of its tax-exempt purposes.
- d) Annually acknowledge by the completion of the Conflict of Interest Disclosure Form within 30 days, that he or she is in compliance with the intent of this

Policy; when “off-cycle” events arise, complete and submit the addendum to the Conflict of Interest Form within 30 days.

3. **Policy Objectives.** The primary objective of this Policy is to enhance the objectivity and transparency of Foundation activities by providing an explicit methodology for individuals who participate in Foundation projects or other Foundation activities. This methodology requires individuals to: (a) identify and disclose any relationships, as defined below, that may cause or be perceived as causing a potential “conflict of interest” affecting the individual’s participation in the activity, and (b) resolve all conflicts of interest in a manner that is respectful to members and interested parties, and respectful of confidentiality to the extent appropriate.
4. **Disclosure of Potential Conflicts.** All members of the Foundation are required to list, on the *Conflict of Interest Disclosure Form*, any actual or potential conflicts of interests involving personal or familial, business, commercial, or institutional relationships, competing interests, or conflicts related to work with industry or a potential competitor such as other patient communities or registries. This disclosure is required *prior* to participating in any Foundation activities. This Disclosure is to be provided to the HR Director; in turn, the Adjudication Process will be addressed by the General Counsel.

In the event you are uncertain as to the appropriateness of listing a particular conflict of interest, list it. Such information, including information provided on this form, will be held in confidence except when a conflict of interest is determined to exist, in which event it will be disclosed to the Board of Directors and as otherwise required by law and generally accepted accounting principles.

For purposes of clarity, the following definitions are provided to help you decide whether a real or potential conflict of interest exists.

- *Business Relationships:* One in which a member of the Foundation or a member of his or her immediate family (i) serves as an officer, director, employee, partner, or trustee, (ii) is the actual or beneficial owner of more than one percent (1%) of an entity or such lesser interest that places the trustee, director, officer of the Foundation or a member of his or her family in a position to influence decisions of an entity, or (iii) otherwise regularly engages in a course of business with an entity that could reasonably be considered to give such trustee, director, officer or member of his or her family a financial stake in the financial performance of such entity.
- *Commercial Interests:* The Foundation conforms to the American Academy of Continuing Medical Education (ACCME) definition of commercial interests. The ACCME currently defines commercial interest as “any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients”. The ACCME excludes providers of clinical service directly to patients.

- *Industry Relationships:* Receiving industry funding to consult, lecture, participate in industry scientific advisory boards, conduct research, or provide other services. Some researchers and content experts, or their institutions, have proprietary interests in a substance, technology, or process that has resulted from their work. Some experts serve as paid witnesses in legal proceedings or as consultants in litigation. Such relationships produce potential conflicts of interest (COI) that may compete with activities performed on behalf of a professional organization.
- *Competing interests:* Personal, intellectual or academic relationships that interfere with an individual's ability to objectively consider or interpret the full breadth of available data or alternative points of view. This may include the inability to review a grant or project proposal objectively due to competition for funding, timing of publication or professional stature.

## 5. **Internal Review of Conflicts.**

- All completed Annual Disclosure Forms are to be submitted to the Human Resources Director for review and determination of the potential of "competing interests" or a conflict of interest.
- The completion and submission of a Disclosure Form is to be completed and submitted within 30 days of when an "off-cycle" event or activity is identified that may be a real, potential, or perceived conflict of interest.
- If no real or potential conflicts are reported, the Disclosure Form will be filed and maintained within Human Resources.
- If the Disclosure Form reflects a real or potential conflict, the Disclosure Form will be forwarded to the Foundation's General Counsel for review and preliminary determination of how to manage or eliminate the conflict. In the interim, until a determination is made, the individual who may have a conflict of interest must recuse him/herself from discussions on topics where there is a conflict.
- The General Counsel will notify the involved party of the determination, in writing, giving him or her the opportunity to discuss the appropriate course of action.
- Following this process, the General Counsel may elicit input from an appropriate "subject matter expert" (either internal or external) before making the final determination (in writing) for managing or eliminating the conflict.
- If the involved party wishes to appeal the final determination, the matter may be brought to the attention of the Chairman of the Board (if a Board Member, MAB Member, Research Advisory Forum Member, or CEO) or to the CEO (if a Staff Member, Staff Medical Advisor, Ambassador and Support Group Leader).
- In the event of an appeal, the Chairman or CEO (as applicable) will consider the written facts and circumstances presented and may interview the involved party,

the General Counsel, and other “subject matter experts” as may be appropriate before making a final determination in writing.

- The final written determination, which may include requiring a member to recuse him or herself from discussions, votes, or other situations where a conflict of interest exists, or prohibiting an involvement, will be provided to the Human Resources Director for inclusion in the Disclosure File.

## **6. Examples**

- Member of the MAB is approached by The France Foundation to work on a CME project. The activity needs to be disclosed, but it is not a conflict of interest.
- A Staff Medical Advisor is approached about working on another PF registry and is considering participation. This activity needs to be disclosed and it is a conflict of interest because the knowledge the Staff Medical Advisor has about the RCCN means that there exists a real conflict that could encumber independent decision-making or compromise one’s ability to act in the best interests of the Foundation. This is probably a prohibited activity.
- A Staff Medical Advisor is approached about working on a non-PF registry and is considering participation. This activity needs to be disclosed and it is not considered a conflict of interest.