

## ***IMEDS Conflict Of Interest Policy***

### **Purpose**

This policy relates to conflicts of interest related to management of the Innovation in Medical Evidence Development and Surveillance (“IMEDS”) program by the Reagan-Udall Foundation for the FDA (“RUF”). The purpose of this policy is 1) to identify and address real or apparent conflicts of interest relating to the IMEDS program; 2) to ensure that decisions about IMEDS and the use or disposition of assets available through IMEDS are made honestly, prudently, and solely for the benefit of the IMEDS project; and 3) to ensure that such decisions are not influenced by any private profit or other personal benefit to “Interested Persons” (as defined below) who take part in a decision or whose decision may affect the Interested Person him/herself or a “Related Person” (as defined below) In addition to actual conflicts of interest, Interested Persons are also obliged to avoid actions that could be perceived or interpreted to be in conflict with IMEDS’ best interests.

This Policy does not supersede and is, and is intended to be, consistent with RUF’s Bylaws and other policies adopted by RUF relating to the disclosure and management of real or potential conflicts of interest.

The procedures below are established to avoid the possibility that Interested Persons do not receive an inappropriate benefit from their actions. Interested Persons should disclose their interest in entities doing business with or related to IMEDS and refrain from participating in decisions affecting transactions between IMEDS and those other entities without approval. Such relationships do not necessarily preclude participation in transactions so long as the relationship is clearly disclosed and the RUF retains the authority to manage any real or perceived conflict of interest.

### **Definitions**

1. **IMEDS** – the Innovation in Medical Evidence Development and Surveillance initiative, managed by RUF.
2. **Interested Person** – shall mean members of the IMEDS Steering Committee or IMEDS Scientific Advisory Board, and any person assisting such members, including RUF employees, contractors, detailees, consultants, advisors and unpaid volunteers or interns.
3. **Related Person** - shall mean with respect to any Interested Person either
  - (i) a natural person who is a spouse, minor child, adult child, employer, business partner, or any other person with whom the Interested Person is negotiating or has any arrangement concerning employment or partnership; or (ii) any corporation, partnership, limited liability company, trust or other non-federal entity (a) in which the Interested Person or any natural person specified in clause (i) hereof holds a position of, or similar to, director, officer, employee, partner, stockholder, trustee, or beneficiary of a trust (other than a *de minimis* ownership interest), or (b) with which the Interested Person or any natural person specified in clause (i) hereof is negotiating or has any arrangement concerning potential employment or partnership.

4. **Interest** – shall mean, with respect to any Interested Person or Related Person (i) compensation including direct or indirect remuneration as well as gifts or favors that are not insubstantial, or (ii) any non-financial interest arising out of service to any organization involved in matters related to IMEDS (e.g., unpaid membership on outside Boards).
5. **IMEDS Business Transaction** - shall mean past, present or future plans to do one or more of the following relating to IMEDS:
  - a. initiate, make the principal recommendation for, or approve a purchase, contract, or grant;
  - b. recommend or select a vendor, contractor, grantee;
  - c. draft or negotiate the terms of such a transaction; or
  - d. participate as a reviewer on Peer Review Committee.

## **Disclosure**

**IMEDS Steering Committee and Scientific Advisory Committee.** Each member of the IMEDS Steering Committee and Scientific Advisory Committee shall provide RUF upon appointment, and annually thereafter, with a signed statement listing any Interest in any entity that is regulated by the Food and Drug Administration. Such statements will be reviewed by the Executive Director of RUF and RUF counsel to determine whether any action, including recusals from certain matters, is appropriate in light of any disclosures.

In addition, any person, who may be involved in or aware of an IMEDS Business Transaction in which there is an actual or possible conflict of interest involving an Interested Person or Related Person shall promptly notify the RUF Executive Director, who shall promptly notify the Chairman of the IMEDS Steering Committee (or if the conflict relates to the Chairman, the Vice-Chair of the Committee). The Chairman or Vice-Chair will then consult with the RUD Executive Director and RUF counsel to determine what, if any action, to take in light of the actual or potential conflict and will refer any recommended action to the full Steering Committee for a vote. The decision by the Steering Committee on these matters will rest in its sole discretion.

Each Interested Person has the affirmative responsibility to report to the Committee Chair any and all knowledge of any action or conduct that appears to be contrary to this Conflict of Interest Policy.

### **Examples of Areas where Conflict of Interest May Arise**

1. Persons and firms supplying goods and services used in connection with IMEDS;
2. Persons and firms from whom property or equipment is leased for IMEDS;
3. Persons and firms who are, or who are planning to, make gifts, purchases or sales of real estate, security, or other property in connection with IMEDS;
4. Competing organizations;
5. Agencies, organizations, and associations that affect IMEDS; and
6. Related persons, friends and employees.

**Potential Conflicts of Interest (Financial) include, but are not limited to:**

1. Contracting to purchase goods and services or property from a participant in IMEDS or a director, officer, staff member of such participant, or a Related Person of any of the foregoing;
2. Engaging in any financial, business or other relationships with current or potential recipients of grants made in connection with IMEDS;
3. Owning stock or holding debt or other proprietary interests in any third party dealing with IMEDS;
4. Engaging in any outside activity, such as serving, either in a paid or unpaid capacity, on the board of organizations that are current or potential recipients of grants made in connection with IMEDS;
5. A Related Person being associated with a recipient of a grant made, or the counterparty to a contract made, in connection with IMEDS;
6. Accepting in any form whatsoever, any remuneration, compensation or gift from current or potential recipients of grants made, or counterparties to contracts made, in connection with IMEDS, or providing or giving gifts or favors to others where these might appear designed to influence improperly others in their relations with IMEDS;
7. Using the time, personnel, equipment or supplies devoted to IMEDS, or the good will associated with IMEDS, for other than activities, programs and purposes approved in connection with IMEDS.
8. Serving as a paid consultant for an entity that has a financial interest in decisions made as part of the IMEDS program.

**Potential Conflicts of Interest (Non-Financial) include, but are not limited to:**

1. An Interested Person who seeks preferential treatment in connection with IMEDS for himself, a Related Person, or business associate.
2. An Interested Person who for personal reasons makes use of confidential information obtained in connection with IMEDS for his/her own benefit, or for the benefit of a Related Person, business associate, or other organization.

**Violations of Conflicts of Interest Policy**

If the IMEDS Steering Committee has reason to believe that an Interested Person has failed to disclose an actual or potential conflict of interest, it shall inform the person of the basis for such belief and afford the person an opportunity to explain the alleged failure to disclose.

If, after hearing the response of the Interested Person and making such further investigation as may be warranted in the circumstances, the Steering Committee determines that the Interested Person has knowingly or intentionally failed to disclose an actual or possible conflict of interest, it shall refer the matter to the RUF Board, which may take appropriate disciplinary and corrective action.

**Federal Employees**

The RUF Conflicts Policy shall not apply to federal employees participating in IMEDS because (i) such federal employees are subject to Department of Health and Human Services (“HHS”) and Government-wide conflicts of interest requirements and (ii) in the judgment of RUF, such HHS and Government-wide requirements are adequate to address potential conflicts of interest that may arise in connection with a federal employee’s role in IMEDS.