

## ***IMEDS Confidentiality Policy (Attachment X)***

This confidentiality policy governs the treatment of all Confidential Information (as that term is defined below) relating to the Innovation in Medical Evidence Development and Surveillance (“IMEDS”) program administered by the Reagan-Udall Foundation for the Food and Drug Administration (“RUF”).

All Confidential Information (as defined below) is privileged and strictly confidential. RUF Board members, members of the IMEDS Steering Committee, members of the IMEDS Scientific Advisory Board, RUF staff (including RUF employees, consultants, detailees, contractors, and unpaid volunteers or interns) connected with IMEDS, and IMEDS outside collaborators (collectively, "Participants") shall maintain the confidentiality of all Confidential Information and only use such Confidential Information in connection with the IMEDS project. This Confidentiality Policy is not intended to prevent disclosure where disclosure is required by law.

Participants must exercise good judgment and care at all times to avoid unauthorized or improper disclosures of Confidential Information. Conversations in public places, such as restaurants, elevators, and airplanes, should be limited to matters that do not pertain to Confidential Information or to other information of a sensitive or confidential nature. In addition, Participants should be sensitive to the risk of inadvertent disclosure and should, for example, refrain from leaving Confidential Information on desks or otherwise in plain view where it could be seen by unauthorized persons.

In the event that any individually identifiable health information is collected by Participants, Participants must comply with all applicable federal requirements governing the use of such information, including but not limited to the Health Insurance Portability and Accountability Act of 1996.

For purposes of this Confidentiality Policy, “Confidential Information” means documents, associated materials and information provided to a Participant in connection with IMEDS, materials prepared by reviewers in connection with the IMEDS peer review process, and discussions and communications (whether written or oral) associated with IMEDS; *provided, however*, that any of the foregoing that (i) can be demonstrated to have been in the public domain or publicly known at the time of disclosure to the Participant; (ii) can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to the Participant from another source prior to disclosure thereto in connection with his or her association with RUF; (iii) becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the Participant; (iv) can be demonstrated to have been independently developed or acquired by the participant without reference to or reliance upon such Confidential Information; (v) is required to be disclosed by law; or (vi) the communication or disclosure of which is determined by the Commissioner of FDA, in writing, to be essential to address an imminent threat to the public health, shall not be deemed to be Confidential Information. When distributing information among Participants, it is the responsibility of the Participant distributing the information to determine whether such information is Confidential Information and to clearly label all Confidential Information as such.

A Participant shall not use Confidential Information, as defined in this Policy, for his/her own benefit or profit and will not share such Confidential Information with others unless specifically instructed or authorized to do so in writing by RUF as part of his/her assigned duties.

A Participant shall destroy or return all Confidential Information in written form after the completion of his or her assignment.

Breaches of this Confidentiality Policy could result in irreparable injury and damage to individuals involved in IMEDS and/or the RUF, for which the individual and/or the RUF may have no adequate remedy at law. Upon such breach, the RUF and the relevant individual would be entitled to seek injunctive relief in addition to any other remedy to which it may be entitled at law or in equity.