SOPP 8101.3: Participation in or Planning of Outside Regulatory and Scientific Events

Version: 7
Effective Date: November 27, 2019

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I. Purpose

A. This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to follow to participate (either as a speaker or as part of a planning committee) in outside regulatory and scientific meetings, conferences, workshops, seminars, symposia, educational programs, public information campaigns, etc. (hereafter referred to as “events”).

B. This SOPP also describes the process for approval of individuals to represent CBER in such events.

II. Scope

This SOPP applies to participation in events that are external to CBER.

III. Background

A. CBER Staff receives numerous requests for participation in and planning of outside events. It is important that CBER continue to meet the needs of our stakeholders, including regulated industry, by participating in events that provide a forum for the exchange of information. It is equally important for staff to keep abreast of state-of-the-art developments in the scientific community and participate in the open exchange of such information.

B. The Division of Manufacturers Assistance and Training (DMAT), Office of Communication, Outreach and Development (OCOD) is the designated contact in CBER for providing recommendations to Center staff on the appropriateness of participating in and planning of outside events, as well as recording, processing and tracking staff participation in such events. DMAT also serves as the Center liaison for Agency coordination of outside events.

C. The enactment of the Small Business Regulatory Enforcement Fairness Act requires government agencies to report to Congress on education, training and outreach activities directed to small business. Tracking of participation by CBER staff in outside events will help satisfy the reporting requirements of the Act.

IV. Definitions

A. Events – Refers to meetings, conferences, workshops, seminars, symposia, educational programs, public information campaigns, etc.

B. Outside Events – Events designated outside the purview of the Department of Health and Human Services (DHHS) (i.e., sponsored by organizations outside DHHS).

C. Planning Outside Events – Participation on a planning committee for outside events; i.e., developing the agenda, identifying potential speakers or otherwise making commitments on behalf of CBER.

D. Non-Federal Sources – Refers to any organization, association, corporation, or individual, or any governmental unit other than the Federal Government.

E. Regulatory Events – Refers to events that focus on FDA regulations, policies, procedures, etc.

F. Sponsor of Event – Refers to event organizer(s)/planner(s).

G. Prohibited Source – Any person or entity that:
a. is seeking official action by the agency planning the event;

b. does business or seeks to do business with that agency;

c. conducts activities regulated by that agency;

d. has interests that may be substantially affected by the performance or nonperformance of the official duties of an employee of that agency, or

e. is an organization the majority of whose members are described in (a) through (d) above.

V. Policy

A. Invitations for Center staff to participate in outside events should be forwarded to DMAT.

B. DMAT will review, record, track the request, and make recommendations to the appropriate Office/Division Director with regard to CBER staff participation.

VI. Responsibilities

A. Division of Manufacturers Assistance and Training

1. Serves as the CBER contact point and processes all requests for CBER participation in outside events.

2. Informs the event sponsors of CBER's expectations:

- Sponsors should submit a formal request for staff participation in an event
- Requests should include the name(s) of speaker(s) (if known) and topic/subject matter; event date, title and location; meeting agenda (if available); anticipated attendance; and targeted audience.
- Requests should be submitted as early as possible in the planning process.

3. Records and tracks incoming requests for staff participation in outside events.

- Records will be kept of all requests received by CBER staff for participation in and/or planning of outside events. This record will provide DMAT with an event history, which will include sponsors, locations, topics/subject matter, dates and speakers requested.

4. Forwards incoming request(s) to appropriate CBER staff for consideration and confirmation of availability to participate in the event.

5. Requests a Conflict of Interest review by the Office of Management for event invitations received which may present a conflict or inappropriate appearance.
   - This review is to ensure a clear understanding by CBER participant(s) of what they may or may not accept from the meeting organizer, or whether or not it is appropriate for staff to participate in the event.
   - In the event the request is for a Center employee to participate in the planning for an event, the Conflict of Interest review will include a determination of the need for CBER to prepare a Co-sponsorship Agreement.

6. Provides a status report on CBER event participation to CBER management as requested.

7. Reviews the topic requested to determine if it has been identified as a current priority, or is directly related to the Center's mission.
   - If the topic requested has not been identified as an outreach priority, DMAT consults with appropriate Center staff/management to determine if a need exists for staff participation in the event.

B. CBER Office Directors/Division Directors
Make final decision (approval/disapproval) regarding participation in outside events by personnel in their respective offices.

C. CBER Staff
Directs inquiries from outside organizations inviting staff to participate in an outside event, either as a speaker or member of a planning committee, to DMAT.

VII. Procedures

A. Receive request for CBER staff participation in an outside event. **[DMAT]**

B. Review the request for Center and topic appropriateness. **[DMAT]**

C. Contact the appropriate office(s) within CBER, and work with the organizers to provide the support most acceptable to all parties. **[DMAT]**

D. Inform the organizers of final decision and provide the speaker(s) contact information, if accepted. **[DMAT]**

VIII. Appendix

N/A

IX. References

A. References below may be found on the Internet:

1. FDA Staff Manual Guide 2340.1: Acceptance of Payment for Travel Expenses from Non-Federal Sources
2. FDA Staff Manual Guide 1455.1: Authority to Authorize and Approve Local and Domestic Travel, Cash or In Kind Travel, Transportation, and Related Allowances - Civil Service Personnel
3. HHS Memorandum, Co-Sponsorship Guidance
4. 21 CFR 10.65 Administrative Practices and Procedures
5. United States Office of Government Ethics, Standards of Ethical Conduct for Employees of the Executive Branch
6. Synopsis of the Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Monser	N/A (Reviewed by Template Coordinator)	November 27, 2019	7	Technical Update to current formant/font and correct hyperlinks
Loni Warren H.	Chris Joneckis, PhD	August 27, 2018	6	Updated to new SOPP format. Content made current
Loni Warren H.	Robert Yetter, PhD	August 3, 2005	5	Replaces Dear Colleague letter with Procedures for Requesting Speakers information
Loni Warren H.	Robert Yetter, PhD	November 11, 2004	4	Technical change to update to current organizational chart.
Seamus O'Boyle	OCTMA	July 22, 2004	3	Replaces SOPP 7201. No change to SOPP content.

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Seamus O'Boyle	Office of Communication, Training and Manufacturers Assistance (OCTMA)	October 1, 2000	2	Periodic Update of SOPPs
S. Schneider	Mark Elengold	February 26, 1999	1	New document published at the request of OCTMA