POLICY AND PROCEDURES

OFFICE OF COMMUNICATIONS

CDER Network Of Experts

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PURPOSE

This MAPP outlines the process for engaging through the Network of Experts (NoE) with external clinical, scientific, and engineering organizations to obtain expertise and broaden staff exposure to scientific, clinical, medical, and other viewpoints, especially in areas of emerging science and pioneering technologies. This document also describes the process by which CDER staff may utilize the CDER NoE program.

BACKGROUND

The purpose of the NoE is to provide CDER staff with access to external scientific, clinical, and medical expertise to supplement existing knowledge and expertise.

CDER's NoE is designed to be an additional tool for gathering external expertise. The NoE program allows CDER staff to tap into a network of external scientific experts upon defining a scientific question. The NoE cannot be used when CDER staff has a need for policy advice.

CDER's NoE may be used to address scientific questions during mission-related activities such as premarket review, postmarket surveillance, or product recalls. The NoE may be used as a tool to provide a more complete view of the evolving scientific landscape.

There are three categories of CDER's NoE issue requests:

- **Category A**: A general topic within the field of Engineering, Science, or Medicine or a disease-based question.
- **Category B**: Practical experience within a specific approved product or product line or specified medical indication.
- **Category C**: A topic related to pending submissions for a specific product or group of specific products.

The NoE can be used when CDER staff has a need for:

- Access to external scientific, medical, and engineering expertise to address mission-related scientific, clinical, or technical questions.
- Further scientific understanding from external sources not available through other existing mechanisms. This may include access to expertise in emerging fields.
- Information from individual experts.

The NoE is not a replacement for existing mechanisms for obtaining external scientific or clinical expertise, such as advisory committees, public meetings, workshops, hearings, scientific literature and conferences, or information from other federal employees.

POLICY

- CDER's NoE is governed by a series of written agreements with external organizations. These organizations include academic institutions and professional scientific, engineering, and medical organizations.
- Participating organizations have agreed to recruitment and screening of appropriate experts upon request.
- Experts (e.g., scientists, engineers, and clinicians) who engage with CDER staff through the NoE will not provide policy advice to CDER.
- Experts who participate in the NoE can provide specific scientific, engineering or medical information, or academic perspective, based on their real-world experience to inform CDER staff decision-making.

- Experts participating in the NoE will not be Special Government Employees (SGEs). CDER may use the NoE process for matters that are the subject of Advisory Committee meetings though SGEs cannot be consulted.

RESPONSIBILITIES

CDER Division Director (or designee)

- If applicable, approves or disapproves NoE requests based on the criteria provided in section PROCEDURES II below and clears questions for the NoE within three business days of receiving the Issue Outline from the Office NoE Liaison.
- Ensures questions are scientific and necessary for CDER staff to effectively complete their work.
- Appoints one or more Office NoE Liaison(s) to work with the CDER NoE Lead and facilitate Office staff working with the NoE.
- Identifies the appropriate CDER staff to participate in the NoE call.

CDER Subject Matter Expert (SME)

- Initiates the NoE request and draft of the Issue Outline.
- Writes the questions for the NoE.
- Provides the Issue Outline to the Office NoE Liaison.
- Communicates with the CDER PASE NoE Lead to identify the appropriate organizations for the NoE call.
- Reviews Expert's CV and COI forms and selects Expert accordingly.
- Attends all calls with NoE Experts.
- Completes the NoE Post Call Survey within five business days of the NoE call.
- Reviews NoE call transcript and provides edits, if applicable, within two weeks of receiving the transcript.

Office NoE Liaison, or designee:

- Receives NoE request and Issue Outline from CDER SMEs in the Office.
- Forwards the following to the Office Director, or designee, for clearance:
    - Request to use the NoE.
    - The completed Issue Outline.
- Collaborates with the CDER PASE NoE Lead. Shares documents, as appropriate.
- Attends all calls with NoE Experts.
- Completes the NoE Post Call Survey within five business days of the NoE call.

Professional Affairs and Stakeholder Engagement (PASE) Director

- Appoints CDER NoE Lead. The CDER NoE Lead will be a staff member in PASE.
- Provides final approval of Issue Outline.

CDER PASE NoE Lead

- Receives, tracks, and coordinates requests to utilize the NoE.
- Reviews the Issue Outline to determine whether the NoE is the appropriate mechanism to respond to the request. Provides alternative mechanism to address the request, if needed.
- Reviews the Issue Outline received from an Office NoE Liaison. Sends the Issue Outline to the PASE Director for approval.
- Collaborates with the Office NoE Liaison. Shares documents, as appropriate.
- Coordinates and initiates contact with the NoE organizations.
- Consults with CDER's Office of Regulatory Policy (ORP), Division of Information Disclosure Policy (DIDP) and Office of Translational Sciences (OTS) Strategic Partnerships and Technology Transfer (SPT2) Program, to ensure disclosure of information and legal documentation are appropriate when a request falls under Category C.
- Sends the Issue Outline and Conflict of Interest (COI) paperwork to selected external organizations with potential NoE Experts.
- Receives Expert's Curriculum Vitae (CV) or resume and signed and dated COI paperwork from the representative in the NoE Organization.
- Shares Expert's CVs or resumes and COI paperwork with Office NoE Liaison.
- Secures an FDA-approved transcriptionist to transcribe the NoE call.
- Schedules and facilitates the NoE call, following all guidelines outlined in this document.
- Sends the NoE Post Call Survey to the Office NoE Liaison and Office SMEs to complete within five business days of the NoE call.
- Verifies the archival of NoE call materials: Transcripts, Experts CVs, COI forms, and Issue Outline documents to CDER's NoE secure portal.
- Uploads all relevant documents to the appropriate permanent electronic record system as needed.

CDER PASE Project Manager (PM)

- Assists the CDER PASE NoE Lead in receiving, tracking, and coordinating requests to utilize the NoE.
- Places all NoE call materials: Transcripts, Experts CVs, COI forms, and Issue Outline documents in CDER's NoE secure portal.
- Assists the CDER PASE NoE Lead in uploading all relevant documents to the appropriate permanent electronic record system as needed.
- Maintains the archived information from all NoE activities, as per National Archives Records Administration (NARA) requirements.

CDER OTS Strategic Partnerships and Technology Transfer (SPT2) Program

- Works with the CDER PASE NoE Lead to evaluate the prospective NoE organizations to ensure that the organization's participation meets the NoE objectives.
- Coordinates negotiation and execution of the NoE Agreement with the NoE organization.
- Provides consultation to ensure disclosure of information and legal documentation are appropriate when a request falls under Category C.

Representative for NoE organization (or designee):

- Signs a NoE Agreement with FDA.
- Works with CDER PASE NoE Lead to provide the Experts requested.
- Provides the CDER PASE NoE Lead the following information within seven business days of receiving the Issue Outline, COI forms, and CV request:
    - List of Experts.
    - Resumes, CVs, or a list of publications of each Expert.
    - Completed and signed COI form from each Expert.

Network of Experts (NoE) Expert

- Sends the completed COI forms, and CV or resume to the representative of the NoE Organization.
- Attends NoE call with CDER SME, Office NoE Liaison, and CDER PASE NoE Lead to answer questions in the Issue Outline.
- If an NoE call cannot occur due to significant scheduling conflicts, the Expert provides written answers to the questions in the Issue Outline.

- Reviews NoE call transcript and provides edits, if applicable, within two weeks of receiving the transcript.

PROCEDURES

I. Submission of NoE Issue Outline

An Issue Outline is required to initiate an NoE request (see Attachment 1).

1. The CDER SME drafts the Issue Outline and ensures the Issue Outline documents the following:
    - A releasable summary of the issue, including releasable background information.
    - A list of proposed questions for the Expert(s).
    - The expertise and experience needed.
    - Deadlines for a response, and proposed timeframes for interactions.
    - The category of the NoE issue request: A, B, or C.
    - The need to disclose confidential commercial information (CCI).
2. CDER SME provides the Issue Outline to the Office NoE Liaison.
3. The Office NoE Liaison forwards the document to the CDER Division Director, or designee, for approval.

II. Acceptance or Rejection of NoE Request

A. Office Clearance of NoE Request

The CDER Division Director, or designee, approves or disapproves the NoE requests within three business days of receiving the Issue Outline, based on the following criteria:

- Is answering this question essential for completing the staff member's work?
- Does the Issue Outline provide sufficient context to address the question?
- Are the requested fields of expertise or experience appropriate to address the question?
- Is the NoE mechanism appropriate for the issue?
- Are other sources of expertise more appropriate for addressing this question?

B. CDER PASE NoE Clearance of NoE Request

1. The Office NoE Liaison submits the NoE request and cleared Issue Outline to the CDER PASE NoE Lead using the CDER NoE webform available on the internal CDER NoE page.
2. The CDER PASE NoE Lead determines if the NoE is the appropriate mechanism for the requested information based on:
    - The nature of the question being asked.
    - How quickly the answer is needed.
    - Other mechanisms already in place for obtaining the answer.
    - If the CDER PASE NoE Lead decides the NoE process is the appropriate mechanism, he or she ensures the questions conform to the criteria detailed in this MAPP.

3. The CDER PASE NoE Lead may meet with the requesting Office and invite the appropriate CDER staff to ensure any outstanding issues are addressed before proceeding with the NoE request, if needed. This optional meeting can be used to clarify the NoE process and expected timelines.
4. The CDER PASE NoE Lead forwards the NoE request to the PASE Director for approval. The CDER PASE Director, or designee, approves or disapproves of NoE requests within 3 business days of receiving the Issue Outline.

III. The Call for Expertise

After the Issue Outline has been cleared by both the CDER Division Director and the PASE Director, the CDER PASE NoE Lead emails the representative(s) in the NoE organizations for appropriate Experts. The request includes:

- The Issue Outline.
- The appropriate Gratuitous Service and Conflict of Interest (COI) forms (see Attachments 4 - 7).
- A target due date for submitting the requested documentation.

Note: If there is no existing or prior NoE Agreement on file for a requested organization, then CDER SPT2 sends Attachment 3 (Network of Experts Agreement) to the representative of the organization to vet the organization and execute the agreement. The Issue Outline and additional documents can only be sent to an organization that has an active NoE Agreement.

IV. NoE Response to Expertise Call

The representatives in the NoE organizations will take no more than seven business days to:

- Issue an email request for Experts. The request includes the Issue Outline as well as Gratuitous Service and COI forms provided by CDER.
- Ask the prospective Experts to forward their CVs or resumes, and required completed forms, to the organization's NoE representative.
- Forward the collected information and forms to the CDER PASE NoE Lead.

V. Expert Selection

CDER PASE NoE Lead receives the requested information on Experts from the representative in the NoE organization within seven business days of the call for expertise.

1. The CDER PASE NoE Lead reviews the information received for each Expert and ensures the information is complete.
2. The CDER PASE NoE Lead sends the list of Experts, CV and COI documents to the Office NoE Liaison, or designee, who then forwards the documents to the CDER SME staff for their review and final decision on selecting and meeting with an Expert (refer to section VI below).
3. The Office NoE Liaison notifies the CDER PASE NoE Lead which Experts were selected by the CDER SME staff.

CDER gathers and manages information on actual and potential conflicts included in the COI form. Experts are asked to self-identify potential conflicts of interest.

VI. Setting up the NoE call

The CDER PASE NoE Lead proceeds with contacting the selected Experts to schedule the NoE call. Though there is no limit to the number of organizations the requesting CDER Office can solicit, a NoE request can include no more than nine Experts. There is only one Expert per call.

VII. Expert Consultation Conference Call

Conference calls with NoE participants are highly structured. Each 60-minute call has only one expert.

1. The CDER PASE NoE Lead (or designee) begins each call by reading the NoE Rules Statement. (Attachment 2)
2. The CDER PASE NoE Lead (or designee) initiates introductions of the conference call participants.
3. The Expert is given agenda time. During this time the CDER SME asks one or more specific questions and allows the Expert to provide his or her expert viewpoint.
4. A transcription service creates a detailed transcript of each call. (Note: Offices may also choose to generate separate records of the NoE call.)
5. The CDER PASE NoE Lead (or designee) circulates the transcript from the NoE call, with any supplementary written materials submitted by the Expert(s), to the Expert and CDER staff who participated in the call. A two-week period is allowed for editorial review. The transcript will be considered final record if no edits or changes are requested by the Expert or CDER staff at the end of the two-week period.

VIII. Post - Expert Consultation Conference Call Activities

1. The CDER PASE PM or CDER PASE NoE Lead (or designee) archives the Expert consultation materials on a secure internal portal. Materials to be archived include:
    a. The Issue Outline.
    b. A complete list of names of Experts consulted, with their CVs and COIs.
    c. The NoE call transcript.
    d. Any supplementary materials.
2. If the request for expertise was made in reference to a pending application or is used in connection with other regulatory actions that require administrative records, the NoE call transcript may become part of an action package archived in CDER's appropriate permanent electronic record. The CDER Office is responsible for making this determination and uploading to the appropriate permanent electronic record as needed.

3. Certain related records, such as the names of the participating organizations, the names of the individual participating Experts, and transcription of the conversations with individual participating Experts, may be releasable to the public in response to Freedom of Information Act (FOIA) requests.
4. The CDER PASE NoE Lead (or designee) asks the respective Office SME and Office NoE Liaison to complete the NoE Post Call Survey within five business days of the conference call.

IX. Time Limitations.

Completed Confidential Disclosure Agreements (CDA) and COI forms are valid for six months. If the services of the Experts are required for more than six months, a new screening application is necessary. The CDER SME contacts the identified Expert through the CDER PASE NoE Lead as often as needed to address scientific, engineering, or medical issue(s) identified in the Issue Outline, for as long as the COI and CDA are in effect. Any additional Expert meeting or exchange within this time period is documented by the CDER PASE NoE Lead.

REFERENCES

1. FDA, 2022. Center for Drug Evaluation and Research, MAPP 4151.8 Rev.1, Equal Voice: Collaboration and Regulatory and Policy Decision Making in CDER.
2. FDA, 2022. Center for Drug Evaluation and Research, MAPP 6001.1, Rev.1, Special Government Employees Representing Sponsors Before CDER.
3. FDA, 2019. Center for Drug Evaluation and Research. MAPP 7610.1, CDER Records Management.
4. FDA, 2008. Office of the Commissioner, Guidance for Industry: Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members.

DEFINITIONS

Advisory Committee: Panel of independent Experts that provide advice on scientific, technical, and policy matters to the Agency for the evaluation of regulated products.

CDER Subject Matter Expert (SME): CDER Reviewer, Project Specialist, Project Manager, Compliance Officer, or Safety Officer who identifies an issue and requests to use the NoE.

Confidential Commercial Information (CCI): Valuable data or information used in a business that is held in strict confidence. CCI is not disclosed to the public.

Conflict of Interest (COI): This term means that because of other activities or relationships with other persons or organizations, *i)* a person is unable or potentially

unable to render impartial assistance or advice to the Government, or *ii)* the person's objectivity in performing the contract is or might be otherwise impaired, or *iii)* the person has or might acquire an unfair competitive advantage.

External expertise: Refers to expertise provided by members associated to organizations outside the FDA (i.e., academic institutions, professional organizations, other US governmental entities).

Gratuitous Service and Conflict of Interest (COI) form: Completed by the NoE Expert, this form discloses known or potential conflicts of interest, and acknowledges the Expert will provide services without compensation.

Issue Outline: A formal outline describing the issue that CDER is interested in receiving feedback on from NoE Experts.

Network of Experts (NoE) Agreement: A legal agreement that governs the exchange of proprietary or confidential commercial information.

Network of Experts (NoE) Expert: A person who is a member of a participating NoE professional scientific, medical, engineering, or academic organization or institution and who agrees to provide feedback to CDER on the specified Issue Outline.

Network of Experts (NoE) Organization: A professional scientific, medical, engineering, or academic organization with a signed NoE Agreement with FDA. As part of the NoE Agreement, the organization agrees to identify the Expert(s) and present the names of prospective Experts to the CDER NoE Lead, or designee.

Special Government Employees (SGEs): A person appointed on a full-time, part-time, or intermittent basis to serve with or without compensation for not more than 130 days during any period of 365 consecutive days.

Sponsor: The New Drug Application (NDA) or Biologics License Application (BLA) applicant or the Investigational New Drug Application (IND) sponsor.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/23/15	Initial	n/a
10/7/21	Rev. 1	Clarified text. Added Records Management requirements. Updated technology. Updated References section.

2/1/24	Rev. 2	Made administrative changes. Changed the responsibilities section. Updated the procedures section to reflect current process. Updated References section. Removed NoE Post Call Survey attachment.

ATTACHMENT 1: Issue Outline Template

1. What is the scientific issue and the reason for seeking input from the Network of Experts? Include a description of the issue. An abbreviated form of this summary will be included in the Network of Experts external package. We recommend separating releasable information from non-releasable information.
2. What questions are you asking the Experts?
3. What type of expertise and/or experience is needed? Are there alternative areas of expertise that would be helpful? Are there specific Network of Experts organizations you would like to request?
4. Does the issue area/question relate to a pending application? If so, provide information on the application and the status of any relevant PDUFA, GDUFA, OMUFA, and BSUFA deadlines. When is the information needed?
5. Will the communication with the Expert(s) include discussion of any non-public information? If the discussion could include any non-public information, inform the Network of Experts Lead so he/she can consult with CDER's Office of Regulatory Policy, Division of Information Disclosure Policy to ensure that the disclosure of such information is appropriate and that all participants complete a Confidential Disclosure Agreement (CDA). Any information related to a pending submission, including its existence, can be considered non-public information. No non-public information will be shared with Experts without the explicit consent of the owner of the information, such as the sponsor, applicant, or FDA.
6. In which of the following three categories does this issue belong?

   Category A: Topic within a field of Engineering, Science, or Medicine or a Disease-Based Question: examples include current state of knowledge in congenital heart disease, latest trends in pharmacogenomics, current technical limitations in disease modeling, latest advances in proteomics, current state of knowledge in human factors.

   Category B: Practical experience with a specific approved product or product line or specific medical indication: examples include current best practices for cardiovascular imaging, current practice guidelines for using HbA1C tests for diagnosis of diabetes and tyrosine kinase inhibitor therapy, approved risk evaluation and mitigation strategies (REMS).

   Category C: Topic related to pending submissions for a specific product or group of specific products: examples include questions regarding an unapproved product used in a clinical study that is currently under review by the Agency in an active IND or a pending NDA/BLA.

ATTACHMENT 2: NoE Rules Statement

The CDER Network of Experts (NoE) is intended to provide a setting for an informal exchange of scientific expertise.

- "Experts are expected to disclose any potential conflicts of interests they may have.

- Experts are asked to confine their responses to answers that represent their scientific or clinical opinion based on experience. They are not asked to provide policy advice or unfounded opinions.

- We want to hear the Expert's point of view. Experts are expected to give robust answers to the questions posed.

- Records related to the NoE and NoE conversations, including information discussed here today and the names of participating Experts, may be released to the public by FDA. An Expert should not be doing this for any personal gain or publicity, but rather to voluntarily provide expertise. The participation or involvement of the Expert in a Network of Experts call is not an endorsement by FDA or HHS. If for any reason you believe you are unable to comply with these ground rules, please let the NoE Lead know and remove yourself from the discussion."

ATTACHMENT 3: Sample NoE Agreement

This Network of Experts Agreement ("Agreement") is made by and between the **Food and Drug Administration** ("**FDA**"), an agency of the United States Government, and the _____("Collaborator" or "Organization Name"). Collectively or individually, the FDA and Collaborator are referred to as "Parties" or "Party," respectively.

WHEREAS, each Party is interested in collaborating on the Network of Experts program, a joint project for efficiently exchanging information and knowledge with leaders in emerging fields of science and pioneering technologies, including _____ (e.g., internal medicine); and

WHEREAS, the Parties propose to establish a mechanism that provides FDA staff with rapid access to Collaborator's members who have scientific, engineering, or other medical expertise to supplement existing knowledge and expertise within FDA ("Experts"); and

WHEREAS, the primary objective here is to permit FDA rapid access to various scientific viewpoints from individual Experts with experience in new medical technologies, because doing so will further the Parties' mutual goals of having more innovative, safe, and effective drug medical products on the market.

NOW, THEREFORE, in consideration of the foregoing, and intending to be legally bound hereby, the Parties agree as follows:

I. Definitions.

1. "FDA Material" means the Issue Outline and any other materials provided by FDA to Collaborator to undertake the purpose of this Agreement, including materials that may have been originally submitted to FDA by sponsors, reporting facilities, health care providers or other third parties.

2. "Collaborator Material" means information provided by the Collaborator or its individual experts in the course of undertaking this Agreement.

3. "Issue Outline" means the background information provided by FDA that includes the issue area, the reason for seeking input from the Network of Experts, whether the issue relates to a pending submission/application, and whether confidential information will be discussed.

II. Roles and Obligations of the Parties.

1. Upon receipt of a request from FDA, Collaborator agrees to use its best efforts to provide one or more Experts to FDA with relevant expertise who can discuss the Issue Outline, according to the instructions identified in Appendix A, not included in this MAPP.

2. The Expert will provide individual scientific views, based on his or her own particular scientific expertise. The Expert or Experts will not formally or informally provide group opinions, advice, or recommendations to FDA.

3. Neither Collaborator nor its Expert(s) will use FDA Material as the basis for its own work or publications, or base a patent application, copyright, or any other intellectual property on FDA Material.

III. Confidential Information.

1. For the purposes of this Agreement, "Confidential Information" includes FDA Material and Collaborator Material and any scientific or business data that a Party marks as confidential and proprietary, except for data that:
    a. had been published or otherwise is publicly available at the time of disclosure to the receiving Party; or
    b. was in the possession of or was readily available to the receiving Party from another source prior to the disclosure; or
    c. became publicly known, by publication or otherwise, not due to any unauthorized act by the receiving Party; or
    d. the receiving Party can demonstrate it developed independently, or it acquired without reference to or reliance upon such Confidential Information.

2. Each Party agrees to accept the Confidential Information and employ all reasonable efforts to ensure that the Confidential Information of the other Party remains secret and confidential. The receiving Party will not disclose, reveal, or give Confidential Information of the disclosing Party to anyone, except employees, members, consultants, or contractors of the receiving Party who have a need for the Confidential Information to carry out the purpose of this Agreement, or as required to be disclosed by law, regulation, or court order. Such employees, members, consultants, or contractors will be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information must be treated accordingly. This obligation will continue regardless of whether this agreement is terminated at a future date.

IV. General Terms.

1. This Agreement will remain in force for five (5) years. The term may be extended, and the provisions of this Agreement may be modified only by written amendment.

2. This Agreement does not create an agency relationship between the Parties, or confer any employee or other rights on the Experts. Experts will be providing services to FDA on a gratuitous basis.

3. This Agreement may be terminated by either Party for any reason by providing written notice to the other Party at least thirty (30) days prior to the desired termination date. This Agreement may be terminated immediately upon the mutual, written agreement of both Parties.

4. By entering into this Agreement, FDA does not directly or indirectly endorse any product or service. Collaborator agrees not to claim, infer, or imply endorsement by the Government of the United States of America, the Department of Health and Human Services, the FDA, or any employee or subunit, of the research, the Collaborator, or any of Collaborator's products or services.

5. By entering into this Agreement, Collaborator does not warrant or otherwise guarantee the expertise of the Experts referred to FDA, nor the statements of fact or opinions that they provide to FDA. Rather, Collaborator provides such Experts in good faith, based upon their reputations in the field and their respective representations.

6. The construction, validity, performance, and effect of this Agreement will be governed by federal law as applied by the federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

7. The Agreement may be executed in one or more counterparts, each of which shall be considered an original, and all of which taken together shall constitute one and the same instrument.

ATTACHMENT 4: Gratuitous Service and Conflict of Interest Forms

The non-writable PDF Gratuitous Service and Conflict of Interest Forms are attached to this MAPP.

The categories are as follows:

- **Attachment 5: Category A.** A general topic within the field of Engineering, Science, or Medicine or a disease-based question.
- **Attachment 6: Category B.** Practical experience within a specific approved product or product line or specified medical indication.
- **Attachment 7: Category C.** A topic related to pending submissions for a specific product or group of specific products.

ATTACHMENT 5: Category A Gratuitous Service and Conflict of Interest Form

Gratuitous Service and Conflict of Interest Forms (to be completed and signed by Expert based on applicable category.)

Category A – for questions about a general topic within the field of Engineering, Science, or Medicine or a disease-based question, please submit the following form with your Issue Outline. Please fill in all blanks with a brief description of the topic to be discussed. This form will be considered self-certified, and FDA will conduct periodic audits of the forms to confirm the accuracy of the information gathered.

FDA's Network of Experts Self-Certification Form – Gratuitous Service and Conflict of Interest

I, [Name of Expert], will serve as an Expert as described in the attached Network of Experts Agreement and its Appendices without compensation. I hereby affirm that I will not expect nor demand compensation for my service and waive any future claims against the U.S. government for this gratuitous service. I hereby acknowledge and understand that I will provide an accurate listing of my current financial interests and other financial involvements to the extent requested below.

This is not a Federal Advisory Committee. FDA is seeking your individual scientific viewpoint regarding (insert scientific issue area) but is not seeking group opinions, recommendations, or advice on any matter.

We are requesting you carefully consider all of the information made known to you by FDA, and then certify that to the best of your knowledge and belief any real or potential (perceived) conflict of interest in discussing (insert scientific issue area) with FDA.

Typically, whether a conflict of interest exists or not is considered under the "reasonable person" theory. That is to say that if a reasonable person were provided all of the relevant facts of the matter would he/she conclude that because of any of your **business, financial, research, personal or professional society/organizational relationships** you could not be objective in discussing (insert scientific issue area) with FDA. Although the bolded items do not represent a complete list of potential areas of conflict, listed below are some of the most common. If you believe you have any potential conflicts, please list them. Conflicts of interest are not prohibited in the Network of Experts, but full disclosure must be provided.

General Potential Areas of Conflict

1. Financial interests are held by you, your spouse, dependent child, business partner or anyone with whom you have a close personal relationship related to medical products/devices.

2. Employment positions you currently hold (or are under negotiation) that are related to medical products/devices.

3. Provision of consulting services regarding any medical products/devices.

4. Patents you or your spouse hold related to medical products/devices.

_____ _____

Expert Signature Date

ATTACHMENT 6: Category B Gratuitous Service and Conflict of Interest Forms

Category B – for questions about practical experience within a specific approved product or product line or specified medical indication, please submit the following form with your Issue Outline. Please fill in all blanks with a brief description of the topic to be discussed. This form will be considered self-certified, and FDA will conduct periodic audits of the forms to confirm the accuracy of the information gathered.

FDA's Network of Experts Self-Certification Form – Gratuitous Service and Conflict of Interest

I, [Name of Expert], will serve as an Expert as described in the attached Network of Experts Agreement and its Appendices without compensation. I hereby affirm that I will not expect nor demand compensation for my service and waive any future claims against the U.S. government for this gratuitous service. I hereby acknowledge and understand that I will provide an accurate listing of my current financial interests and other financial involvements to the extent requested below.

This is not a Federal Advisory Committee. FDA is seeking your individual scientific viewpoint regarding (insert scientific issue question), but is not seeking group opinions, recommendations, or advice on any matter.

We are requesting you carefully consider all of the information made known to you by FDA, and then certify that to the best of your knowledge and belief you do not have any real or potential (perceived) conflict of interest in discussing (insert scientific issue question) with FDA.

Typically, whether a conflict of interest exists or not is considered under the "reasonable person" theory. That is to say that if a reasonable person were provided all of the relevant facts of the matter would he/she conclude that because of any of your **business, financial, research, personal or professional society/organizational relationships** you could not be objective in discussing (insert scientific issue question) with FDA. Although the bolded items do not represent a complete list of potential areas of conflict, listed below are some of the most common. If you believe you have any potential conflicts, please list them. Conflicts of interest are not prohibited in the Network of Experts, but full disclosure must be provided.

General Potential Areas of Conflict

1. Financial interests are held by you, your spouse, dependent child, business partner or anyone with whom you have a close personal relationship related to medical products/devices.

2. Employment positions you currently hold (or are under negotiation) that are related to medical products/devices.

3. Provision of consulting services regarding any medical products/devices.

4. Patents you or your spouse hold related to medical products/devices.

Topic Specific Potential Areas of Conflict

Any other financial, business, or scientific relationships you are aware of that might cause a reasonable person to question your impartiality when discussing (insert scientific issue area).

Some things to consider regarding the question above:

Current financial interests related to (insert scientific issue area) held by you, your spouse, a member of your household, or a relative with whom you have a close personal relationship.

Current employment positions or paid consultative services you currently hold (or are under negotiation) or held during the last calendar year related to (insert scientific issue area).

Service as an officer or Board member for any organization that has a financial interest or has taken a public position within the past 12 months on (insert scientific issue area).

Expression of a public opinion on matters related to (insert scientific issue area) either through speaking or writing that went beyond basic scientific interpretation.

Service as an expert witness related to (insert scientific issue area).

_____ _____

Expert Signature Date

ATTACHMENT 7: Category C Gratuitous Service and Conflict of Interest Forms

Category C – for questions about a topic related to pending submissions for a specific product or group of specific products, please submit the following form with your Issue Outline. Please fill in all blanks with a brief description of the topic to be discussed. The Agency will follow the appropriate legal procedures to protect the confidential information from the sponsor regarding a specific submission or product. This form cannot be self-certified.

Please indicate if the Network will be asked to discuss proprietary, or otherwise confidential, information. In this case, discussion will require a release signed by the company before the convening of the Network and the experts will be required to complete a CDA.

FDA's Gratuitous Service and Conflict of Interest Form

I, [Name of Expert], will serve as an Expert as described in the attached Network of Experts Agreement and its Appendices without compensation. I hereby affirm that I will not expect nor demand compensation for my service and waive any future claims against the U.S. government for this gratuitous service. I hereby acknowledge and understand that I will provide an accurate listing of my current financial interests and other financial involvements to the extent requested below. If access to Confidential Information, as defined in the attached Network of Experts Agreement, from FDA is required in the performance of my services under this agreement, I hereby agree to abide by the terms set forth in the attached Confidential Disclosure Agreement.

This is not a Federal Advisory Committee. FDA is seeking your individual scientific viewpoint regarding (insert scientific issue area) but is not seeking group opinions, recommendations, or advice on any matter.

We are requesting you carefully consider all of the information made known to you by FDA.

Typically, whether a conflict of interest exists or not is considered under the "reasonable person" theory. That is to say that if a reasonable person were provided all of the relevant facts of the matter would he/she conclude that because of any of your **business, financial, research, personal or professional society/organizational relationships** you could not be objective in discussing (insert scientific issue area) with FDA.

Please indicate below if you have any of the following potential conflicts. Where potential conflicts exist, please provide a detailed list.

General Potential Areas of Conflict

1. Financial interests are held by you, your spouse, dependent child, business partner or anyone with whom you have a close personal relationship related to medical products/devices.

2. Employment positions you currently hold (or are under negotiation) that are related to medical products/devices.

3. Provision of consulting services regarding any medical products/devices.

4. Patents you or your spouse hold related to medical products/devices.

Topic Specific Potential Areas of Conflict

Any other financial, business, or scientific relationships you are aware of that might cause a reasonable person to question your impartiality when discussing (insert scientific issue area).

Some things to consider regarding the question above:

Current financial interests related to (insert scientific issue area) held by you, your spouse, a member of your household, or a relative with whom you have a close personal relationship.

Current employment positions or paid consultative services you currently hold (or are under negotiation) or held during the last calendar year related to (insert scientific issue area).

Service as an officer or Board member for any organization that has a financial interest or taken a public position within the past 12 months on (insert scientific issue area).

Expression of a public opinion on matters related to (insert scientific issue area) either through speaking or writing that went beyond basic scientific interpretation.

Service as an expert witness related to (insert scientific issue area).

_____ _____

Expert Signature Date