

	<p>Network of Experts: Expert Utilization</p>	<p>Abbreviated Standard Operating Procedure (SOP)</p>
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1. Purpose

The purpose of the Network of Experts (Network) is to provide staff in the Center for Devices and Radiological Health (CDRH) with rapid access to external individuals (Experts) with unique expertise in science, engineering, or medicine to supplement knowledge and expertise within the Center.

This document describes the process by which CDRH staff may utilize the Network of Experts program.

2. Scope

The Network can be used when CDRH staff have a need for:

- rapid access to scientific, engineering or medical expertise to address work-related questions,
- scientific, engineering, or medical knowledge from external sources that cannot be obtained via other mechanisms, e.g. access to expertise in emerging fields, and
- information from individual experts, as opposed to the advice or recommendations from a group of experts collectively.

The Network is not intended to:

- provide advice on policy matters

- replace existing sources of external scientific and clinical expertise (e.g. Special Government Employee (SGEs) and public meetings)

Questions should be limited to those that are scientific, engineering, or medical in nature and necessary for CDRH staff to effectively complete their work and cannot be obtained by using the existing mechanisms outlined above. The Network is not a replacement for our SGEs and the important advisory and consultative work they perform while serving on advisory panels and carrying out homework assignments. CDRH staff should not use the Network process for matters that are the subject of a panel meeting which has been announced in a Federal Register Notice.

The Network may be used to address scientific, engineering, and medical questions during a variety of mission critical activities, such as: premarket review, post-market surveillance, and product recalls. In addition to currently existing mechanisms, the Network provides a means for CDRH staff to rapidly access thought leaders in emerging fields of science, engineering and medicine.

3. Background

The Network of Experts program is designed to provide CDRH staff with rapid access to external, individual, scientific, engineering or medical expertise. The goal of the program is to allow CDRH staff to efficiently access a virtual network of experts within two weeks of defining a scientific, engineering, or medical question.

The Network is governed by a series of written agreements with external organizations, which may include professional scientific, engineering, and medical organizations as well as academic institutions. Participating organizations facilitate the rapid recruitment and screening of appropriate Experts upon request from the Network of Experts Coordinator (See Section 4.1).

Expert scientists, engineers, and clinicians may not provide policy advice to the Center. However, experts in the Network can provide specific scientific, engineering or medical information based on their tangible real-world experience that may aid CDRH staff in reaching their own informed conclusions. In addition, the Network provides an important resource for furthering the general scientific, engineering or medical knowledge base of CDRH staff.

Experts in the Network provide services to FDA on a gratuitous basis. Prior to providing any gratuitous services to the Agency, Expert(s) must agree in writing that (1) they will receive no compensation and (2) waive any future claims against the government for their services. The Network of Experts program is available to the FDA. Other Centers within FDA may also use the Network of Experts to access external scientific, engineering, or medical expertise through prior agreement with CDRH. Though the Network of Experts program resides within

CDRH, other Centers within FDA may choose to use the program to access external scientific, engineering, or medical expertise through a prior agreement.

4. Roles and Responsibilities

- 4.1. **Network of Experts Coordinator.** The Network of Experts Coordinator is the primary contact for the Network of Experts program and manages the enrollment of new organizations with the External Expertise and Partnerships (EEP) technology transfer staff and utilization of the program by CDRH.
- 4.2. **CDRH Requestor.** The CDRH Requestor is the staff member who submits a description of the issue requiring external expertise to their branch chief or division director.
- 4.3. **Network of Experts Office Liaison.** A Network of Experts Office Liaison is a representative in each CDRH office who works with the Network of Experts Coordinator in the clearance the appropriateness of questions for the Network.
- 4.4. **Network of Experts Organization.** A Network of Experts Organization is a professional society that has been enrolled in the Network of Experts program. Each organization has a Network Liaison that is the main point of contact for the Network of Experts calls and interacts directly with the Network of Experts Coordinator.
- 4.5. **Technology Transfer Liaison.** The Technology Transfer Liaison arranges for the drafting and negotiation of the Network of Experts Confidential Disclosure Agreement (CDA), and consults with the Advisory Panel Staff in regard to clearance of the Experts prior to contacting the Experts.

5. Procedures

5.1. Overview

The Network of Experts is designed to be simple and straightforward to use. CDRH staff will submit a brief description of the issue requiring external expertise and the type of expertise required to their branch chief or division director. Once this request has been cleared by the branch chief and Network of Experts Office Liaison, it will be submitted by the Network of Experts Coordinator to the appropriate Network of Experts partner organization. Organizations will respond with a list of potential experts and their supporting information [curriculum vitae (CV), Conflict of Interest (COI, etc.)] within one week. CDRH staff may then contact one or more Experts from said list. CDRH staff should identify the need for external expertise and submit a request to the Network as early as possible to help ensure the availability of the appropriate Expert(s). If it is appropriate for the expert to become a SGE, please consult the CDRH advisory panel staff for possible SGE recruitment.

5.2. Preparation of the Network of Experts Issue Outline

The Network of Experts Issue Outline (Issue Outline) is an **internal** document, which should be no longer than two pages. CDRH Staff should complete the Issue Outline and forward the document to their branch chief, or their designee, who must give final approval, disapproval, or request revision of the Issue Outline within three days of receipt. The Issue Outline is designed to collect the following information:

1. a releasable summary of the issue, including releasable background information (as needed)
2. a list of proposed questions for the Expert(s)
3. the expertise and/or experience needed
4. if the questions pertain to a pending application, deadlines for a response and proposed timeframes for interactions
5. the question category
6. the need to disclose confidential commercial information (CCI)

5.3. Prepare the Network of Experts External Package

The Network of Experts Coordinator will prepare the Network of Experts External Package. The Network of Experts External Package shall include: (i) a revised version of the Issue Outline and (ii) a filled-in COI form for the question category and issue

The External Package will be sent to the external organization's Network liaison. The External Package is a summary of the cleared from the Issue Outline.

- i. Prepare the revised Issue Outline
- ii. Identify the issue category and the corresponding COI form. The COI form must be completed, signed, and dated by each prospective external Expert before the Expert's information is forwarded to the CDRH staff member placing the request.

The COI form for the Network of Experts is stratified by the specificity of the inquiry. A general question about a field of medicine or an area of science or engineering requires a different level of conflict of interest scrutiny than a question about a specific manufacturer's device. In the case of the former, there are fewer potential financial conflicts than in the case of the latter. Although conflicts reported by experts should be carefully considered by the

CDRH staff member placing the request (CDRH Requestor); a self-reported conflict does not necessarily bar the agency from using that Expert. , CDRH staff should take into consideration the existence of actual and potential conflicts when choosing to seek information from the external Expert. If a significant conflict does exist however, the CDRH requestor should select a different external Expert or Experts. If the call to the Network of Experts involves a Category C question, the CDRH requestor should work with their Technology Transfer Office Based Liaison to obtain a waiver from the sponsor and arrange for the drafting and negotiation of the Network of Experts CDA, and consult with Advisory Panel staff in regard to COI clearance of the Experts prior to sending the external package or contacting the experts.

5.4. Clearance of the Issue Outline and External Package

5.4.1. Branch Chief/Division Management Clearance of the Issue Outline and External Package

Individual CDRH Offices will determine the level of office management clearance required for a Network of Experts request. Initial clearance of the Issue Outline and External Package must take place within three days receipt. Branch chiefs / division management should conduct the initial review of the Issue Outline and External Package using the following criteria:

- 1) *Is this question important for completing the CDRH staff member's work?*
- 2) *Does the Issue Outline provide sufficient context to address the question?*
- 3) *Are the requested fields of expertise and/or experience appropriate to address the question?*
- 4) *Are there any additional matters that need to be considered?*

5.4.2. Network of Experts Office Liaison Clearance of the Issue Outline and External Package

After initial management clearance, the Issue Outline and External Package should be emailed to the Network of Experts Office Liaison for clearance. The Network of Experts Coordinator should be copied on the message. The Network of Experts Office Liaison will confirm whether the Network is the appropriate mechanism for addressing the issue. If appropriate, the Network of Experts Office Liaison should verify that the Issue Outline conforms to the criteria laid out within this SOP. The Network of Experts Coordinator will submit a summary of the issue for publication in the Center's Weekly Pulse. Additional CDRH staff who wish to participate in upcoming Network of Experts calls should contact the originating CDRH staff member.

5.5. A Call for Expertise

The Network of Experts Coordinator will send an email request for expertise to the Network organization(s). The request will include:

- the Network of Experts External Package (revised Issue Outline and COI form See Section 5.2 above); and
- if applicable, a Confidential Disclosure Agreement (CDA). The CDA is only required if confidential information will be discussed; and
- a proposed timeframe for interactions between CDRH staff and the external Expert(s); and
- a clear deadline for receipt of Expert CVs and completed COI forms (and CDAs –if applicable).

Upon receipt of a request from FDA, Network organizations will issue a request for Experts that includes the External Package (revised Issue Outline and COI form See Section 5.2 above. Volunteering Experts will be asked to submit their CVs, completed COI forms and CDA forms (if required) to their Network organizational liaisons. Said liaisons are expected to return CVs, COIs and CDAs (if applicable) one week after receiving a call for expertise from CDRH.

5.6. Expert Screening and Selection

There is a multi-tiered vetting process. There is the initial screening performed when their representative organization is enrolled as a Network organization.

A screening will be conducted at the time a specific question is posed. Experts will be asked to provide their CV, completed category-specific COI, and, if required, CDA forms. CDRH's goal is to gather information on actual and potential conflicts of interest and to ensure these are managed appropriately. Experts will be asked to self-certify in regard to their potential conflicts of interest. Self-certifying COIs will be randomly audited by CDRH ethics staff.

The CDRH Network of Experts Coordinator will receive Expert CVs, the appropriate, completed COIs and any other information from Network organizations within one week of placing a call for expertise to the Network organizations. The CDRH requestor will use this information to select Experts with appropriate expertise and an acceptable degree of Conflict of Interest (if any). The CDRH requestor may choose to consult with one or more Experts. The CDRH requestor will contact selected Experts to notify them of their selection and to schedule a teleconference. Invitations to the Expert teleconference should also be extended to the referring branch chief, and any Office Director.

5.7. Expert Discussion

If the CDRH requestor intends to consult with multiple experts about the same issue, they may choose to contact each expert separately, or convene a group conference call. The CDRH

requestor may not ask the same questions of more than 9 experts within any 12 month period.

Expert conference calls will be highly structured:

- The Network of Experts Coordinator will begin each call by reading the purpose and rules statement of the Network of Experts.
- This opening will be followed by introductions after which, the Network of Experts coordinator will confirm that each Expert has completed the screening questions and appropriate clearance.
- If more than one Expert is participating in a call, the CDRH requestor must ensure that discussion between participants does not occur.
- Each Expert will be given a unique time on the agenda to allow CDRH to seek the expertise of each expert individually. Each Expert will be asked to provide his or her individual scientific, engineering, or medical expertise. The Network of Experts will provide a transcriptionist who will be present throughout the call and subsequently provide transcripts to Network of Experts.
- Within two weeks, the transcript, along with any supplementary written materials submitted by the Experts will be circulated to the Experts and CDRH staff who participated in the telephone conference. Experts will be given one week to concur that the records are an accurate representation of their statements.
- After concurrence, the CDRH requestor will submit the finalized meeting notes to the Network of Experts Coordinator.
 - Expert consultation materials, including the Issue Outline, complete list of names of Experts consulted, meeting notes, post-call evaluation form and any supplementary materials, will become part of the administrative record if the request for expertise was made in reference to a pending application or are used in connection with other regulatory actions that require administrative records. Certain records related to the Network of Experts, such as the names of the participating organizations, the names of the individual participating experts, and notes of the conversations with individual participating experts, may be releasable to the public in response to request for records pursuant to the Freedom of Information Act (FOIA), and FDA may choose to proactively release this information under certain circumstances.
- Time Limitations:
 - Completed CDA and COI forms will be considered valid for six (6) months unless a CDRH requestor indicates that they are needed for longer.
 - In no case shall the CDA and COI forms remain valid for more than nine (9) months.

- If the services of the Experts are required for longer than nine (9) months, a new screening application will be necessary.

Within reason, the CDRH requestor may contact the identified Expert(s) 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 (if needed) are in effect.

- The CDRH Network of Experts Coordinator will periodically provide feedback to Network organizations regarding their Experts' participation.

6. Definitions/Glossary [N/A]

7. References/Supporting documents

¹ Please see also the FDA draft guidance on advisory panels

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf> .

² "Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073449.htm>

³ "When FDA Convenes an Advisory Committee meeting"

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/LawsRegulationsGuidance/default.htm>

⁴ Panel Review of Premarket Approval Applications #P91-2

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm>

⁵ "PMA Review Process"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm>

8. Records

- Issue Outline
- External Package (includes any completed forms: COI, CDA)
- Expert consultation materials, including the Issue Outline, complete list of names of Experts consulted, meeting notes, post-call evaluation form and any supplementary materials
- Expert(s) must agree in writing that (1) they will receive no compensation and (2) waive any future claims against the government for their services.

