Network of Experts- Expert Utilization Standard Operating Procedure (DRAFT)

U.S. Food & Drug Administration

The purpose of the Network of Experts is to provide staff at the Center for Devices and Radiological Health (CDRH, Center) with rapid access to scientific, engineering, and medical expertise when it is needed to supplement existing knowledge and expertise within the Center. This program is designed to broaden the Center for Devices and Radiological Health's (CDRH, Center) exposure to scientific viewpoints, but not to provide external policy advice or opinions. CDRH has a tremendous internal cadre of scientific expertise, including over 800 scientists, engineers, and clinicians. Despite this internal resource, it is unrealistic to expect CDRH staff to encompass all of the applicable expertise and experience necessary to fulfill our mission, given the rapidly growing variety and complexity of medical devices. This is particularly true when it comes to new and emerging fields of science and pioneering technologies. In these areas, it is often necessary for our experts to gain further scientific understanding from sources outside of the federal government. The Network of Experts will facilitate this exchange.

Background

Why is a Network of Experts Needed?

Existing Sources of External Scientific and Clinical Expertise:
Currently, CDRH scientists, clinicians and engineers can supplement their knowledge base in several ways:

(1) they convene advisory panel meetings using experts serving as Special Government Employees (SGE's) or have SGE's complete written homework assignments;

(2) they read scientific literature and attend scientific conferences;

(3) they hold public workshops that include scientific experts; and

(4) they reach out to other federally employed scientists outside of CDRH.

In addition, manufacturers and other regulated entities often meet with us and bring experts to supplement or complement our expertise and knowledge base.

Panel Meetings and Homework Assignments:
Our 700+ Special Government Employees (SGEs) are an important resource to the Center. These include national experts that serve in this capacity for 2 or more years. They serve as members of advisory panels/committees and as consultants to the Center. Their service may include participating at a panel meeting on a specific

device or product area and/or providing written answers to agency directed "homework" assignments.

Advisory committees provide independent expert advice to the agency on a range of complex scientific, technical, and policy issues. An advisory committee meeting also provides a forum for a public hearing on important matters. CDRH recognizes that advisory committee meetings demand significant resource commitments by advisory committee members, sponsors and other public participants, as well as for the FDA itself, and should not be used in every circumstance. The agency has developed non-binding recommendations that include factors to consider when deciding whether to refer a matter to an advisory committee,[1] [1] in addition to other information related to the advisory committee process and specific instances in which advisory committees are used by CDRH [2] [2],[3] [3],[4] [4],[5] [5],[6] [6].

SGEs also provide expertise through homework assignments, during which they provide written responses to agency questions and inquiries. Examples of homework assignments include: the review of a product application that does not warrant convening a full panel; a statistical analysis leading to the development of regulatory methodology; a risk/benefit analysis for a specific issue in a product application; and the review of a guidance document that will assist industry and/or agency staff. During a homework assignment 1-3 SGEs are asked to provide individual written responses to one or more questions. CDRH utilizes 60 to 100 SGEs performing over 40 homework assignments a year, and the input they provide is invaluable. However, this process relies upon the existing pool of SGEs, which may not contain experts in specific emerging or unanticipated fields. Staff planning to use panel meetings or homework assignments should keep in mind that advisory panels and homework assignments typically take 3 months to arrange.

Scientific Literature and Conferences, Public Workshops:
Peer-reviewed scientific publications and conferences serve as important tools for every scientist to learn about new fields of research and keep track of research trends. However, conferences can lag behind the latest research or may not occur at the time the scientific question arises within the regulatory context within CDRH.

Public meetings are extremely useful when CDRH wants to get a broad assessment of experts in a field or to serve as a convener of disparate stakeholders to encourage new partnerships and collaborations. However, public meetings are resource intensive and cannot include discussions of confidential information. CDRH has developed an internal Standard Operating Procedures (SOP) that is used to coordinate Public Meetings and Workshop.

Other Federal Expertise:
Generally, non-CDRH federal employee experts can be utilized readily, because all employees of the Executive Branch must comply with government-wide ethics laws and regulations, and are authorized to receive certain non-public or proprietary information. However, each federal agency may have established procedures for how its employees interact with other federal agencies or federal employees. At present, when appropriate, CDRH staff turn to other FDA scientists, such as those at the Center for Drug Evaluation and Research or the National Center for

Toxicological Research; scientists within other branches of the Department of Health and Human Services, such as the National Institutes of Health or the Centers for Disease Control and Prevention; and those not in health-related agencies, such as employees of the National Institute of Standards and Technology.

Some federal employees also serve as advisory panel members and complete homework assignments alongside SGEs. However, just as CDRH cannot fully represent all current and emerging areas of scientific expertise, other federal agencies may not have the specific expertise necessary to address a particular scientific question.

The Network of Experts

What is the Network of Experts?

The Network of Experts program is designed to be an additional tool for gathering external expertise in a rapidly accessible and efficient manner. The goal of the program is to allow CDRH staff to tap into a virtual network of scientific experts within 2 weeks of defining a scientific question that CDRH staff need to address quickly.

The Network will be built on a series of agreements with external organizations. The external organizations will include professional scientific and medical organizations and academic institutions. (Please see the companion SOP on Expert Enrollment for a more detailed description.) Participating external organizations will facilitate the rapid recruitment and screening of appropriate experts on an as needed basis.

These clinicians, scientists, and engineers are not intended to provide policy advice to the Center. But experts in the Network can provide certain scientific information that may aid CDRH staff in reaching their own informed conclusions within the Center. In addition, the Network will serve as an important resource for furthering the general scientific education of CDRH staff.

When to Use the Network of Experts:

Because this Network is designed to provide a resource not otherwise available, questions should be limited to those that are scientific and necessary for CDRH staff to effectively complete their work and are not suitable for using any of the existing mechanisms outlined above. For example, the Network is not a replacement for our SGEs and their important advisory and consultative work as part of advisory panels and homework assignments. Questions for the Network might include those that require expertise that does not reside within the current SGE pool and are time sensitive due to a public health concern that warrants a rapid regulatory action. The Network may be used to address scientific questions during a variety of mission-important activities, such as pre-market review, post-market surveillance, and product recalls. As issues evolve over time the Network is a tool that may be used in addition to existing mechanisms to provide a more complete view of the scientific landscape where needed.

How to Use the Network of Experts:

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 describe the types of expertise required. Once this request is cleared by the branch chief, it will be submitted by the Network of Experts coordinator to the appropriate Network of Experts partner organizations. Organizations will respond with a list of potential experts and their supporting information within one week. In most cases, at that point staff may contact one or more experts from that list. CDRH staff should identify the need for external expertise and submit a request as early as possible to best assure the availability of the appropriate expert(s). If it is appropriate for the expert to become an SGE, please consult the CDRH advisory panel staff for possible SGE recruitment.

Step 1- Submit a Network of Experts Issue Outline
The CDRH staff member provides the following background information to their branch chief, or their designee, for approval. The Issue Outline should be no longer than 2 pages and the branch chief, or designee, must give final approval, disapproval, or request revision of the Issue Outline within 3 days. The Issue Outline should address the following four sets of questions:

1) What is the issue area and the reason for seeking input from the Network of Experts? (Provide a brief description.)

2) (A) Does this relate to a pending application? If so please provide information on the application and the status of any relevant MDUFA deadlines. What is the timeframe of a useful answer? (B) What type of expertise and/or experience is needed? Are there alternative areas of expertise that would be helpful?

3) Will this require the discussion of confidential commercial information? (If so a please see your Tech Transfer Office Liaison (T2OBL) to obtain a release from the sponsor before proceeding.) Will this require discussion of other confidential information? (If the discussion could include *any* confidential information please inform the Network of Experts coordinator so they can ensure that the disclosure of such information is appropriate and that all participants complete a Confidential Disclosure Agreement (CDA). No confidential information will be shared without the explicit consent of the owner of the information, such as the sponsor or FDA.

(A) No trade secrets (TS) or confidential commercial information (CCI) will be shared without the explicit written consent of the owner of the information, such as the sponsor. Please see your Tech Transfer Liaison Office (T2OBL) to obtain a release from the sponsor and a Confidential Disclosure Agreement (CDA) from the Experts before proceeding.

(B) No personal privacy information (PPI) will be shared without the explicit written consent of the person(s) whose privacy interest is implicated.

(C) No information regarding FDA’s deliberative processes, open law enforcement investigations, or other materials protected by the governmental privileges will be

shared without explicit authorization from appropriate FDA officials.

4) Which of the following three categories does this issue belong? A. Topic within a field of Engineering, Science, Medicine or Disease-

Based Question

-Examples- Current state of knowledge in congenital heart disease, latest trends in material science, current technical limitations in whole genome sequencing technology, latest advances in robotics

B. Question about a product line or specific medical indication

-Examples- Current best surgical practices for using gynecological mesh, current practice guidelines for using HbA1C tests for diagnosing and treating diabetes, experiences with percutaneous heart valves

- May include specific questions related to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

C. Specific Product or Group of Specific Products

-Examples- Experience implanting product X

In addition to the Issue Outline, the requesting CDRH staff member should fill in the blanks in the appropriate self-certifying Conflict of Interest form so this can be completed by the prospective external experts.

Step 2- Branch Chief Clearance
Offices are permitted to design their own processes for issuing clearance of requests depending on their structure and how often they use the Network, but questions should receive branch level clearance within 3 days. Branch chiefs are asked to review the Issue Outlines based upon the following criteria:

1) Is answering this question important for completing the 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 additional regulatory concerns that need to be considered? If so please add them to the Issue Outline.

Once these questions have been addressed and the Issue Outline has been cleared, it should be submitted to the Office level Network of Experts representative and the Center level Network of Experts Coordinator. They will determine whether the

Network is the appropriate mechanism for answering the question. If it is, the Office representative should double check that the questions conform to the criteria laid out within this SOP and inform all Office directors of the pending request for expertise. This notification can be done by submitting a short issue summary and the name of the requesting CDRH staff member to the Network of Experts Coordinator so it can be included in weekly Center-wide staff notes. Additional CDRH staff who wish to participate in that discussion with the Network are invited to contact the originating CDRH staff member.

Step 3- A Call for Expertise

The Network of Experts coordinator will send an email request to Network organization(s) for experts with relevant expertise. The request will include the Issue Outline and any clarifying comments added by the branch chief. It should also include a target date for the communication between CDRH staff and the external expert(s) and a clear deadline for submitting supporting documentation. The request will also include an adapted Conflict of Interest form (COI) and, if applicable, a Confidential Disclosure Agreement (CDA). The CDA is only required if confidential information will be discussed. If confidential commercial information will be discussed, the owner of the information must agree to release the information by signing a waiver and the Experts must agree not to disclose the information by signing an appropriate CDA before the conversation(s) takes place.

Network organizations should issue an email request for experts as soon as possible including the Issue Outline and any additional or supporting information provided by CDRH. Volunteering experts will be asked to submit their names, CVs or resumes, and completed COI and CDA forms (if required) to the sponsoring organization within 7 days for submission to CDRH.

The COI form for the Network of Experts will be stratified by the specificity of the inquiry. A general question about a field of medicine or an area of science 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 a conflict may exist that would not necessarily bar the agency from using that expert, staff should take into consideration the existence of actual and potential conflicts when seeking information from the external expert and, when a conflict does exist, may wish to speak to a different external expert or to additional external experts. If the call to the Network of Experts involves a Category C question, please see the appropriate Technology Transfer Liaison for your office to arrange the appropriate CDA and see the Advisory Panel staff for COI clearance of the experts prior to sending any supporting information or contacting the experts.

Step 4- Expert Screening and Expert Convening

All experts will be screened in two ways. There will be the initial screening performed when their representative organization is enrolled as a Network organization (see accompany SOP on Network of Experts Enrollment), but at the time a specific question is posed they will be asked to provide their CV and complete the topic-specific COI and CDA (if required) forms.

For most questions, experts will be asked to self-certify as to their potential conflicts of interest. CDRH aims to gather information on actual and potential conflicts and to ensure these are managed appropriately. Self-certifying COIs will be randomly audited by CDRH ethics staff to make sure we are receiving reliable information. And the small minority of Network conversations that involve confidential information will only be conducted if the owner of the confidential information (e.g., sponsor) grants a release for CDRH to share this information with the external expert.

The requesting CDRH staff member will receive the list of experts, their CV's, the appropriate completed COI and any other information within a week of submission to the Network partner organizations. They are free to use this information to select which experts will best serve their needs and contact those experts directly. Invitations should also be extended to the referring branch chief, and any Office Director or their designee who may have an interest in the topic.

CDRH staff may contact experts individually or, if multiple experts are being utilized, set up a conference call. Conference calls will be highly structured. Each expert will be given a unique time on the agenda, to allow CDRH to seek the expertise of each expert individually.

CDRH staff should begin each call by reading the purpose and rules statement of the Network of Experts. This opening should be followed by introductions at which time it should be confirmed that every expert has completed the screening questions and appropriate clearance. CDRH staff should take detailed notes of the conversations with experts and submit them to their office Network representative. These notes, along with any supplementary written materials submitted by the experts within 2 weeks of the meeting, will be posted on the Network of Experts Traction page by the Office level representative for use throughout CDRH. Experts and participants will be given one week to sign off that the records are an accurate representation of their comments. These materials (including the Issue Outline, names of experts, meeting notes, 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, although they will otherwise remain confidential within CDRH.

Network of Experts Rules Statement
"The CDRH Network of Experts is intended to provide a setting for an informal exchange of scientific expertise. Experts are asked to confine their responses to answers that represent their scientific or clinical experience. They are not asked to provide policy advice or unfounded opinions. We want to hear each individual expert's point of view. Experts are expected to give robust answers to the questions posed, as individuals, and to disclose any potential conflicts of interests they may have. An expert should not be doing this for any personal gain or publicity, but rather to voluntarily provide expertise. If for any reason you believe you are unable to comply with these ground rules please let us know and remove yourself from the discussion."

Periodicity
The CDA and COI forms will be considered valid for 6 months unless a reviewer indicates they are needed for longer. In no case shall the CDA and COI forms remain valid for more than 9 months. If experts are required for longer they will need to complete a new screening application. Staff may contact the identified expert as often as is needed to address the scientific issue(s) identified in the Issues Outline for as long as the CDA is in effect. Each expert conversation within this time period must be noted on the CDRH Network of Experts traction page and meeting notes must be posted.

SOURCE [7]

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