DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 12, 2022

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
Email: foia@sirillp.com

Dear Mr. Siri:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request # 21-01059-FOIA, received on April 13, 2021, seeking:

> "All documents or communications in the possession of Amanda Cohn, to or from below listed members of the Advisory Committee on Immunization Practices ("ACIP"), using any of the following phrases: 'Conflict(s) of Interest(s)'; 'Commercial Conflict(s)'; 'COI'; 'Form 450'; or 'Financial Disclosure.'"

Jose Romero	October 30, 2017 to present
Kevin Ault	October 26, 2017 to present
Lynn Bahta	July 1, 2018 to present
Beth Bell	July 1, 2018 to present
Henry Bernstein	November 27, 2016 to present
Wilbur Chen	December 23, 2019 to present
Matthew Daley	January 4, 2020 to present
Sharon Frey	November 27, 2016 to present
Camille Kotton	December 23, 2019 to present
Grace Lee	July 1, 2015 to present
Sarah Long	December 24, 2019 to present
Veronica McNally	October 31, 2017 to present
Katherine Poehling	July 1, 2018 to present
Pablo Sanchez	July 1, 2018 to present
Helen Keipp Talbot	October 29, 2017 to present

On March 29, 2022, your client agreed to exclude the following:

> *"We are willing to exclude journal articles that contain conflicts disclosures and related language. We are primarily interested in documents that would pertain to the listed members of ACIP in our request. Therefore, if one of those individuals was giving the ACIP presentation with conflict language, we would want that. However, if one of those individuals is simply sending or receiving an ACIP presentation with conflict language relating to another individual/presenter (including a pharmaceutical company employee), we do not need that."*

We located 133 pages of responsive records (77 pages released in full; 49 pages disclosed in part; 7 pages referred to the US Army). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions (b)(4), (b5) and (b)(6).

EXEMPTION 4
Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as the name of private companies and sponsors, proposal title, upcoming projects, campaigns and other activities related to private institutions or external companies, and we have determined that the individuals to whom this information pertains have a substantial commercial or financial interest in withholding it.

EXEMPTION 5
Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include comments, opinions, recommendations, and draft documents.

EXEMPTION 6
Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as names, cell phone numbers, and email addresses. We have determined that the individuals to whom this information pertains has a substantial privacy interest in withholding it.

Please click on the following link to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s814b86d8a7bd4fe181873aa5fb41a243

In addition, the search of CDC files produced seven pages that originated with the US Army. These documents were referred to the US Army for their review and direct response to you. Contact information is provided below.

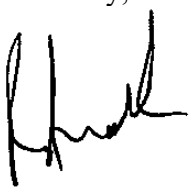
U.S. Army Freedom of Information Act Office
Records Management Directorate
9301 Chapek Rd. Bldg 1458
Fort Belvoir, VA 22060-5605
Email: usarmy.belvoir.hqda-oaa-ahs.mbx.rmda-foia@army.mil

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human

Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by July 12, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#21-01059-FOIA

From: Sharon Frey
Sent: Thu, 20 Feb 2020 15:44:20 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: Duane Stone

Amanda,
I know you are extremely busy but wanted to let you know that Daune Stone has been extremely helpful and available to complete AMS/SAMS and COI.
regards,
Sharon

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Mon, 21 Aug 2017 13:36:40 +0000
To: 'Belongia, Edward A MD'; 'Chip Walter'; 'David Stephens'; 'Dr Jose Romero (RomeroJose@UAMS.edu)'; 'Dr. Allison Kempe (Allison.Kempe@childrenscolorado.org)'; Reingold, Arthur MD (CDC berkeley.edu); Riley, Laura (CDC partners.org); 'Dr. Nancy Bennett (nancy_bennett@urmc.rochester.edu)'; 'Echezona Ezeanolue'; 'Grace Lee'; 'Kelly Moore'; 'Laura McIntosh'; 'Ms. Cynthia Pellegrini (cpellegrini@marchofdimes.com)'; 'Paul Hunter'; 'Peter Szilagyi'; 'Robert Atmar'; 'Tanya Hogan (Romero)'; 'Veronica Girma (Szilagyi)'
Cc: MacNeil, Jessica R. (CDC/OID/NCIRD); Thomas, Stephanie B. (CDC/OID/NCIRD)
Subject: FW: final version
Attachments: Work Group Guidance__Aug 2017.docx

Hi Everyone,

Hope you are doing well. Attached is the finalized WG guidance incorporating your comments. We are going to be officially implementing this guidance over the next couple of weeks. The ACIP Secretariat will be sending out WG member agreements and COIs to all WG members and we will be collecting all forms, so that WG members on multiple WGs only have to sign one agreement.

As ACIP members, you will not need to complete the COI form, but we will ask you to complete the WG agreement, which is a fillable PDF. Please let me know if you have any questions,

Best,

Amanda

Amanda Cohn, MD
CAPT, US Public Health Service
Executive Secretary, Advisory Committee on Immunization Practices
National Center for Immunization and Respiratory Diseases
Phone: (404) 639-6039
Email: acohn@cdc.gov

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES: WORK GROUPS

Standard Operating Procedures: August 2017

Advisory Committee on Immunization Practices Secretariat

Centers for Disease Control and Prevention

Contents

I. Overview of Advisory Committee on Immunization Practices Work Groups

The role of the Advisory Committee on Immunization Practices (ACIP) is to assist the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in development of public policy related to immunization of the civilian population in the United States. ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs are intended to augment the effectiveness of ACIP. The direction, focus, and pace of both ACIP and the individual WGs are guided by CDC and HHS priorities, and by the perceived need for expert advice to inform development of immunization policy.

ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.

Four WGs—the Adult Immunization, General Recommendations, Child/Adolescent Immunization, and Influenza WGs—are permanent. The remaining WGs are task oriented; such task-oriented WGs are developed in response to specific needs and are disbanded when the task at hand has been completed. A list of WGs that are currently active can be obtained from the ACIP Secretariat or the ACIP website.

Q.: When is the appropriate time to establish an ACIP WG?

A.: *ACIP WGs should be established when:*

- *Updates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage).*
- *Licensure of a new vaccine or new indications for existing vaccines are anticipated.*
    - *In general, WGs should begin reviewing data 12-18 months prior to a potential decision on licensure; the length of time required for the WG to review data in anticipation of vaccine licensure will depend upon the complexity of the topic, and the amount of available data that exists.*
    - *Immunoglobulin therapies and/or antimicrobial agents may be considered by ACIP only in relation to control of a disease for which there is a vaccine available or under consideration.*
- *Existing ACIP recommendations should be reviewed on a regular basis, at least every 7 years, and either revised, renewed, or retired with a vote by ACIP. The ACIP Secretariat will establish a WG if review of the recommendations identifies a need to revise the recommendations.*

Each WG operates under specific Terms of Reference (TORs) determined by the WG Chair *(see below)* and WG Lead *(see below)* at the time the WG is formed. The WG Chair and WG Lead, in consultation with other CDC staff, should re-evaluate the TORs annually. TORs should be formalized annually to provide documentation of the WG priorities for each year. TORs will be included on the ACIP website along with a listing of current WG members and will be updated annually.

TORs should be sent to potential WG members as the WG is being formed. Additionally, TORs should be included in the WG Chair presentation to ACIP annually to ensure

transparency. Examples of WG TORs can be obtained from the ACIP secretariat. TORs should be brief (<1 page) and include the following sections:

- Background
- Purpose or Objectives
- Activities

Q.: How frequently should WG TORs be evaluated and/or updated?

A.: *TORs should be re-evaluated when major tasks are completed; when the WG Chair or WG Lead changes; if new issues relevant to the WG arise; when events result in shifts in public heath priorities; and annually between the June and October ACIP meetings.*

II. Work Group Membership

Each WG must include at least two voting members of ACIP, one of whom functions as WG Chair. A CDC subject matter expert (SME) serves as WG Lead, and generally is selected by the concerned CDC program. Other WG members may include ACIP *ex-officio* members, ACIP liaison representatives, and invited consultants. Most WGs should include a representative from CDC's Immunization Safety Office and Immunization Services Division. CDC staff may serve in a supportive or administrative function. During ACIP meeting presentations, CDC staff should be listed on the WG membership slide separately from WG members.

WGs are encouraged to invite a consumer representative to join as an expert consultant. An ideal consumer representative has experience or expertise relevant to the vaccine, disease or condition involved. It is desirable, though not required, that the individual have some degree of familiarity with vaccines. The WG should have a reasonable expectation that the candidate will be able to engage in a dispassionate, unbiased review of data and to comply strictly with the confidentiality requirements placed on all WG members. The ACIP Secretariat can help identify potential consumer representatives.

In order to facilitate participatory discussion among all WG members, consideration should be given to the overall number of WG members, including the invited liaison representatives and consultants serving on the WG, and the expertise each invited consultant brings to the WG. The recommended size of a WG is <15 members, not including CDC staff supporting the WG. WG members may change when the WG TORs change and should be reassessed annually.

Representatives of vaccine manufacturers may not serve as members of a WG but may, at the discretion of the WG Chair and WG Lead, be invited to make presentations to the

group and answer questions. Experts from the private sector who do not represent vaccine manufacturers may be asked to make presentations to the WGs or to participate in discussions at the discretion of the WG Chair and concurrence of WG Lead. Following these presentations, non-WG members are asked to leave so that deliberations are limited to members of the WG.

Participants in WGs are typically limited to U.S. residents, due to the increased cost of international teleconferences, but exceptions occur when expertise is needed from individuals living outside the United States.

Q.: How are WG members selected?

A.: *The process for WG member selection is as follows.*

- *The ACIP Secretariat will, in consultation with the WG Lead, recruit one ACIP voting member to serve as WG Chair, and at least one additional ACIP voting member. The ACIP secretariat will send an inquiry to all current voting ACIP members to assess interest. The ACIP voting members and WG Chair will be determined based on interest, need for expertise on the WG, and balancing ACIP members' available time.*
- *As an ACIP voting member's term expires, the person may continue to serve on the WG in a consultant role at the discretion of the WG Chair and WG Lead.*
- *At the time new ACIP members begin their terms, the Secretariat will request a list of the WGs they are interested in joining and balance these requests with the need to fill voting member positions on WGs. When feasible, the WG Chair will be replaced by an ACIP voting member who has already been on the WG for a period of time. The WG Chair will be chosen by the WG Lead in consultation with the outgoing WG Chair, but should be approved by the Secretariat in order to ensure balance of workload among ACIP voting members.*
- *The WG Lead will be designated by the CDC Center, Institute, or Office with responsibility for the concerned program/vaccine to be considered.*
- *The WG Chair and the WG Lead, in consultation with the ACIP Secretariat, will recruit additional members and consultants for the WG. The WG Chair and the WG Lead should work closely together to determine priorities, process, direction, and timeline for WG activities, again in consultation with the ACIP Secretariat.*
- *In consultation with the WG Lead and WG Chair, the ACIP Secretariat will extend invitations to those ex officio and liaison organizations requested by the WG Chair/WG Lead for representation on the WG. The organization or ex officio agency will designate the individual to represent the organization and agency and can*

request an alternate. When determining the organizations and ex officio liaisons to include, the existing size of and the relevance of the organization or ex officio background to the WG TORs. There should be an FDA liaison for each WG where a new vaccine or indication is under consideration by the WG.

- *The WG Lead should extend requests for subject matter experts to serve as consultants to participate on a WG to ensure there is adequate expertise on the WG to provide evidence-based information to support ACIP deliberations. Consultants should serve as a resource to offer expertise on clinical, programmatic and basic scientific aspects of the vaccine-preventable disease and vaccine, and other factors. If these individuals do not have a conflict of interest (see below), consultants may participate in all discussions and deliberations. If a subject matter expert has a conflict of interest, he/she may participate in scientific discussions but may not participate in policy deliberations.*
- *A temporary consultant can be included in a WG to deal with an important but limited policy topic (i.e., involving interpretation of information and policy discussion over a period of months).*

III. Conflicts of Interest

ACIP WGs serve a key scientific role in support of vaccine policy development by ACIP. Because WGs do not vote on policy recommendations, do not include a quorum of voting ACIP members, and report findings to ACIP rather than the government, procedural requirements of the Federal Advisory Committee Act (FACA) do not apply to WG meetings.

Though FACA procedural requirements do not apply to ACIP WGs, CDC is sensitive to the possibility that conflicts of interest could interfere with the effective functioning of a WG. In order to avoid undue influence or the appearance/perception of a conflict of interest in WG discussions, screening for potential conflicts will be conducted upon establishment of the WG and annual updates will be collected from WG members to ensure that financial or other conflicts are not present and/or have not changed. The ACIP Secretariat will assist WG Chairs and WG Leads with the collection of conflict of interest forms (Appendix); screening of the conflict of interest forms will be conducted by the WG Chair and WG Lead in conjunction with the ACIP Secretariat.

Because ACIP WG participants are most familiar with their own situations, their personal responsibilities include the following: (1) to alert the WG Chair and WG Lead about any possible conflict of interest that may impact perception of impartial and fair activities of WG members and (2) to identify and certify on an annual conflict of interest screening form (a) any aspect of the work of the ACIP WG where a conflict of interest exists, and (b)

that there will not be, and has not been, involvement in the efforts of the WG where participation constitutes a conflict of interest.

The WG Chair or WG Lead, in consultation with the ACIP Executive Secretary (and legal counsel if necessary), may determine that a particular situation involves a conflict of interest or the appearance of a conflict of interest and requires that the potential participant not be involved in some or all of the ACIP WG process. The following guidance and definitions will assist in determining whether a conflict of interest exists. This guidance is not all-inclusive, due to the variety of possible conflicts of interest and the potential for appearance of conflicts of interest.

A financial conflict of interest exists when a participant has an interest in a vaccine product or pharmaceutical company that manufactures vaccines or related products that may affect his/her imputed financial interests or potentially bias his/her approach to development of options for recommendations for use of that vaccine, or of a competing vaccine. A participant who has a conflict of interest for a vaccine for which policy is being developed, or with the manufacturer of such a vaccine, may participate in an ACIP WG only as a consultant with activity restricted by the WG Chair and WG Lead to that essential to provide information critical to the efforts of the WG. Situations in which a WG member, or their institution, has a research grant from a vaccine manufacturer will be evaluated and considered on a case-by-case basis by the ACIP Executive Secretary, WG Chair, and WG Lead.

Regardless of the level of financial involvement or other interest, if the participant feels unable to provide objective advice, he/she must recuse him/herself from the WG activities under consideration. The ACIP WG process relies on the integrity of each participant to disclose to the WG Chair or WG Lead any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

Examples of such situations where a conflict of interest exists where the individual should not serve as a full WG member include:

1. A person or a member of their immediate family is employed directly by a vaccine manufacturer or its parent company. A member of the immediate family includes spouse, domestic partner, or child.
2. A person is a holder of, or otherwise is entitled to royalties or other compensation for, a patent on a vaccine product or process, immunologic agent, adjuvant, or preservative that can be used for a vaccine that may come before ACIP for review/discussion during the anticipated term of the concerned WG.

3. A person holds a paid advisory or consulting role with a vaccine manufacturer to perform work related to vaccines expected to be considered by the WG or companies that manufacture vaccines under the purview of the WG. A person must agree to forego such paid consultation or membership (except participation in clinical trials or service on data monitoring boards) during his/her tenure on the ACIP WG.
4. Federally registered lobbyists may not serve as ACIP WG members.

Examples of potential conflicts of interest should be disclosed and considered for either limiting the role of the consultant or WG member include:

1. WG members are required to disclose participation in conducting clinical trials and service on data monitoring boards.
2. WG members should agree that during their tenure on the ACIP WG, they will not serve as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer.
3. Potential WG members must agree that during their tenure on the WG they will not accept honoraria or travel reimbursement directly from a vaccine manufacturer for attendance at scientific meetings or to present a lecture. They may receive travel reimbursement and/or honoraria for continuing medical education (CME) presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer and where all CME rules and regulations are followed.
4. Except as allowed under 3, potential WG members must agree that during their tenure on the WG they will forego solicitation or acceptance of funds from vaccine manufacturers.
5. Non-financial conflicts (e.g. uncompensated participation in vaccine development, or a researcher identified w/ a particular scientific perspective in a controversial area), should also be disclosed and considered prior to participation.

WG members have an ongoing obligation to bring any new information regarding potential conflict(s) of interest to the attention of the WG Chair and WG Lead. In addition, WG members must inform the WG Lead if they are contacted directly by a representative of a vaccine manufacturer regarding a vaccine under consideration by the WG on which they serve; the WG Lead will then inform the ACIP Secretariat of any such contact.

Q.: How should conflicts of interest be declared during ACIP WG discussions?

A.: *There are two procedures for declaration of conflicts of interest:*

- *Annually, through an annual disclosure form. All WG members, including federal staff, should complete this form, except for voting ACIP members whose potential conflicts are reviewed regularly. An individual who participates in more than one WG can submit one disclosure form to be reviewed by the WG Lead of each WG on which he/she participates.*
- *Prior to each meeting: during roll call, any new potential conflict of interest should be declared.*

Q.: If an SME has received funding for consulting from a pharmaceutical company regarding the vaccine the WG is considering, can he or she still participate as a consultant for the WG?

A.: *ACIP voting members, ex officio members, liaison representatives, or CDC staff who have conflicts of interest may not participate in the WG. People who serve as consultants may participate in the WG despite conflicts of interest if, in the judgment of the ACIP Chair, Executive Secretary, WG Chair, and WG Lead, he or she brings specific expertise that is essential to the efforts of the WG. However, conflicts—both personal and those of their liaison organization (in the case of liaison representatives)—must be declared and recorded. Participation of people with declared conflicts should be restricted by the WG Chair and WG Lead to that necessary for the WG to benefit from the expertise provided by the consultant. No person with an identified conflict of interest should participate in WG endeavors when policy options are drafted in final form for presentation to ACIP or written ACIP policy recommendations are developed.*

IV. Roles and Responsibilities

WG Chair

- Signs annual membership agreement form (see Appendix).
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Works with the WG Lead to identify potential WG members.
- Reviews WG membership to ensure necessary expertise is represented.
- Works with the WG Lead to set an agenda for WG meetings and for timelines of presentations at the full ACIP meetings.
- Provides overview presentation of WG topics at ACIP meetings, and other presentations if needed.
- Co-authors Morbidity and Mortality Weekly Report (MMWR) Policy Notes and Recommendations and Reports (comprehensive ACIP recommendation document).

ACIP Member(s)

- Signs annual membership agreement.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Co-authors MMWR Policy Notes and Recommendations and Reports if authorship criteria are met.

CDC WG Lead

- Works with WG Chair to identify potential WG members.
- Works with the WG Chair to set an agenda for WG meetings and for timelines of presentations at ACIP meetings.
- Coordinates WG meetings, documents roll call, takes minutes or designates another person on the WG (e.g., other CDC staff member) to do so (see Work Group Teleconferences and Meetings, below).
- Coordinates developing agenda proposals, background and briefing documents, and presentations on behalf of the WG for ACIP meetings.
- Leads development of MMWR Policy Notes and Recommendations and Reports documents.
- Attends and participates in monthly WG Lead meetings, routinely uploads documents to the ACIP SharePoint site, completes a timely review of materials, and responds to requests from the ACIP Secretariat.
- Works with the Adult Immunization and Child/Adolescent Immunization WG Lead to review immunization schedule footnotes annually.

Liaison Representatives and *Ex-Officio* Members

- Signs annual membership agreement and conflict of interest forms.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Communicates the perspective of the organization or agency they represent at WG meetings.

Consultants

- Signs annual membership agreement and conflict of interest forms.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Serves as a subject matter expert during WG meetings and calls.

CDC Staff

- Provide administrative support and technical expertise to ACIP WGs.
    - CDC staff on WGs bring subject matter expertise and current professional focus in areas relevant to the goals of the WG. CDC staff are aware of agency priorities, and of current and anticipated policy issues that may arise in association with the focus of each WG and are responsible for working with the WG Lead to ensure that the focus, direction, and timing of WG efforts remain compatible with the needs of CDC and HHS.
- As needed, perform, coordinate, or identify scientific studies and outbreak investigations to address questions that arise regarding vaccine policy decisions; conduct analysis of data addressing efficacy, effectiveness, safety, feasibility, and economic aspects of immunization policy; and participate in evaluation of quality of the evidence, e.g. GRADE review.

V. Work Group Teleconferences and Meetings

WGs accomplish most of their work through teleconferences. When the group is active, a set day and time for routine monthly teleconferences (e.g., 2 PM EST on the last Friday of the month) is usually established. This allows standing teleconferences to be arranged and WG members to anticipate and reserve time for these teleconferences. The frequency of WG teleconferences may change depending on the urgency of the issue(s) being considered by the group. Most WGs meet once per month, but some WGs meet twice monthly, particularly in the time period leading up to an ACIP meeting when the WG may need to meet more frequently.

Most WG teleconferences are held using a call-in number or Skype business teleconference software, and are not operator assisted. The same number may be used for all teleconferences for a particular WG. Teleconferences should not be recorded.

The development of a brief (1-2 page) summary of each WG meeting will facilitate the function of the WG; the taking of minutes is best accomplished by a WG member other than the WG Chair or the WG Lead, in order to allow the WG Chair and WG Lead to lead and manage the meeting effectively. WG meeting minutes are confidential and may be shared by the WG Chair/WG Lead with WG members.

Minutes and slides from each WG teleconference should be uploaded to the ACIP SharePoint sites by the WG Lead on a regular basis (e.g., monthly or quarterly).

When needed, an in-person WG meeting may be arranged either immediately before or after a full ACIP meeting. The Secretariat cannot support these meetings financially, but may be able to reserve a room in the Global Conference Center if a need is identified early. In-person meetings should be used with discretion: ACIP voting members should primarily focus on the public meeting discussions. Please consult with the Secretariat prior to scheduling an in-person WG meeting during an ACIP meeting.

Q.: Are there special considerations for WG meetings in relation to FACA requirements?

A.: *Yes. To be able to operate in closed meetings, ACIP WGs must observe certain guidelines that allow them to function exempt from FACA requirements. ACIP WGs function in a fact-finding role, do not include a quorum of voting ACIP members, and do not vote on policy; they are therefore exempt from FACA requirements.*

As FACA-exempt groups, ACIP WGs are not allowed to render consensus advice or recommendations directly to the Federal government. ACIP WG Chairs, other WG representatives, or the WGs per se are not empowered to speak on behalf of ACIP. Rather, they are utilized by ACIP to gather and organize information upon which ACIP can deliberate and act. Thus, while ACIP WGs can and should examine specific topics in detail and define the issues, including development of options for recommendations, the actual processes of group deliberation terminating in development of immunization recommendations must occur in the open public forum of ACIP meetings in compliance with FACA requirements.

Q.: How are "straw polls" used during WG meetings?

A.: *When there are several different opinions about an issue expressed during a WG meeting or the WG Chair and WG Lead want to ensure all members' perspectives are considered, a "straw poll" can be conducted. A straw poll is not a vote on policy and the goal is not to come to consensus, but rather to document the different opinions of the WG members and help with continued deliberations. Results of straw polls should be kept within the WG, but can be summarized during a presentation at the public ACIP meeting. ACIP voting members, liaison representatives, and consultants with no conflicts of interest should be included in straw polls. Federal employees should not be included. These polls can be done over email or during teleconferences.*

VI. Confidentiality

Unlike ACIP meetings, which are open to the public, WG meetings/teleconferences are not public meetings; data presented during these meetings/teleconferences are often

proprietary and should not be distributed to people other than approved WG members. To ensure confidentiality of data, the following guidelines should be implemented by all WGs.

1. Roll call by the WG Lead should be taken at the start of each WG teleconference to document names of members who are participating; the roll call of participants should be incorporated into brief meeting minutes, which may be compiled by the WG Lead or someone designated to do so by her/him.
2. At the beginning of each WG meeting/teleconference where any material that is not already publically available is being discussed, the WG Lead should state that the meetings are closed and information discussed is confidential and should not be distributed or used in presentations.
3. Only WG members and invited consultants should participate in WG meetings.
4. If the parent organization of a liaison representative wishes to obtain information about WG proceedings, the organization should contact the WG Lead to request a presentation. Liaison representatives serving on WGs should not share WG proceedings, discussion, or slides with the parent organization unless permission is granted by the person who presented this information to the WG.
5. Slides distributed at WG meetings or shown during teleconferences should be marked as confidential and should not be shared with people who are not WG members.
6. To minimize the possibility that slides may be extracted or used outside the WG meeting, PowerPoint presentations should be saved and distributed as .PDF (Portable Document Format) files.
7. WG members should not discuss WG deliberations with anyone representing or employed by a vaccine manufacturer.

VII. Pharmaceutical Companies and Work Groups

Presentations given by pharmaceutical companies to ACIP provide critical information on clinical trials and other studies assessing the safety and efficacy of vaccine products. Guidance for WGs includes:

- If a company and or lobbyist reaches out to a WG member to discuss WG proceedings, the WG member should inform the WG lead immediately.
- When feasible, WGs should provide opportunities for companies with plans to submit a biologics licensing application (BLA) to FDA for a vaccine product to update the WG if new data are available. Relevant updates from companies with products already licensed should be considered when new products are under consideration for use by the WG.

- All information, data, and slides presented during WG calls are confidential. However, all documents related to WGs are subject to FOIA requests. In the event that WG Lead receives a FOIA for materials from some or all WG meetings, the WG Lead will be requested to review and provide all such materials; in consultation with the CDC FOIA Office, the WG Lead may identify items that need to be redacted, e.g. proprietary information (http://intranet.cdc.gov/ocio/about/foia/).
- After pharmaceutical presentations to the WG and time for questions, the company should exit the call. The WG should discuss the implications of the data presented and the importance of presenting the data to ACIP only when company representatives have left.
- All presentation topics by pharmaceutical companies on the ACIP agenda must be presented to the WG prior to presentation at meetings of ACIP.
- The final presentation for ACIP will be more concise, and should be reviewed and approved by the ACIP WG Chair and WG Lead (with consultation from the FDA *ex officio* member serving on the WG, when needed) prior to the ACIP meeting.
- The WG lead (or other CDC staff member serving on the WG) should present a summary of the WG's interpretation of the data presented by the company during the same ACIP session, if appropriate.

Guidance for pharmaceutical companies includes:

- Representatives of vaccine manufacturers should not contact any ACIP WG member for the purpose of promoting a product scheduled for presentation at an ACIP meeting or to suggest recommendations for consideration by ACIP.
- Representatives of vaccine manufacturers should contact the WG Lead when they have data they would like to present to the ACIP WG. Vaccine manufacturers also may be solicited by WG Leads for presentation on specific topics of interest.
- Data that can be proposed for presentation may include data on products under consideration for licensure or post-licensure data on a product that may inform current discussions of the WG.
- The time allocation for the ACIP presentation should be approximately 15 minutes, with an additional 5 minutes for questions. Longer or shorter presentations may be needed; final time allocations will be determined by the WG Lead and the ACIP steering committee during agenda development.
- Presentations must be submitted to the WG Lead 3 weeks prior to the ACIP meeting for review and approval. This provides time for review and incorporation of feedback. If changes are requested, the final presentation should be reviewed by the WG Lead. The deadline for final submission for printing of slides is the Wednesday 1 week prior to the ACIP meeting.

- Any slide outlining the measures used in the studies presented should include the study population, comparison groups, and outcome measures.
- A strengths and limitations slide should be included in the conclusion section of the talk.

VIII. Work Group Resources

The most significant internal resources available to ACIP WGs are the expertise and energy of WG Leads and other CDC staff. In addition, the Secretariat is dedicated to support the work of ACIP WGs including logistics, oversight of issues of science and policy, day-to-day oversight of WGs, and interactions with ACIP membership.

The ACIP Executive Secretary, or "Designated Federal Official," (DFO) is a senior consultant to the Director at the National Center for Immunization and Respiratory Diseases (NCIRD). The DFO is responsible for the committee's overall management and compliance with FACA law.

Additional resources at CDC (e.g., the Office of General Counsel, Federal Advisory Committee Management Branch/Management Analysis and Services Office) are available and can be accessed through the ACIP Secretariat, as well as support for GRADE and cost-effectiveness evaluations.

A monthly meeting of WG Leads is organized by the Secretariat to get input from WG Leads on issues related to ACIP processes and to discuss any challenges or questions specific to a WG among the WG Leads. The Secretariat also provides support to the WG Leads for the ACIP SharePoint site and coordinates annual membership agreement and conflict of interest paperwork.

Funds for support of ACIP activities are limited. Requests for specific support for additional expenses that will enhance ACIP functioning (e.g., extra meeting rooms, equipment, travel of additional persons to ACIP meetings) will be considered by the ACIP Secretariat. CDC routinely supports travel costs for the duration of ACIP meetings for ACIP voting members only. CDC rarely may support travel for invited speakers making presentations during the ACIP meeting, or may agree to provide funding for an additional night for ACIP members. Such requests should be brought to the ACIP Secretariat for consideration on a case-by-case basis, with justification for the increased costs. In some instances, it may be necessary to deny reasonable requests for financial support.

IX. Preparing for ACIP Meeting Presentations

Submitting Agenda Items for ACIP Meetings

Topics for inclusion in the agenda for an upcoming ACIP meeting are solicited by the ACIP Secretariat approximately 3 months before the ACIP meeting, and are due 2 weeks later. Requests for agenda proposals are sent to voting ACIP members, WG leads and ACIP Steering Committee members. A standard template form is used, and includes the following items:

- Justification for inclusion of topic
- Proposed presentations, including topic, presenter, question(s) to be addressed by the ACIP
- Any additional pertinent information

Following compilation of all agenda proposals, the ACIP Steering Committee meets to prepare a detailed agenda, which is then sent back to WG Leads and any others who have submitted proposals. The ACIP secretariat finalizes the draft agenda within 1-2 days of the Steering Committee meeting, and distributes and posts on the ACIP web site. The draft meeting agenda may be modified as needed up to the week of the ACIP meeting.

ACIP Briefing Documents

In advance of each ACIP meeting, a briefing book will be prepared for the CDC Director that includes information on the topics being presented at ACIP and items on which a vote will be taken. The ACIP Secretariat will request briefing documents from WG Leads after the draft agenda has been distributed. Briefing documents will be due 3 weeks prior to the ACIP meeting. A standard template form is used (not to exceed two pages), and includes the following items:

- Topic
- Statement of status of the vaccine or topic and key issues
- Background
- Reason topic is being presented to ACIP: information, discussion, vote, VFC vote (if applicable)
- Policy options
- Consensus of ACIP WG
- Implications of ACIP decision

ACIP Background Materials

In order to prepare voting ACIP members, ex-officio members, and liaison representatives for the issues to be discussed during each ACIP meeting, background materials are

prepared and distributed in advance of each meeting. Background materials can be submitted for all topics on an ACIP agenda, but are required for major issues and items on which a vote will be taken. Background materials will be requested from WG Leads approximately six weeks prior to each ACIP meeting, and will be due two weeks in advance of the meeting.

Background materials will be maintained as confidential, and distributed via CDC's FTP file server, to ONLY the voting ACIP members, ex-officio members and liaison representatives. A cover letter should be prepared and will be placed at the beginning of each section. The cover letter should highlight the information that is most important for the members to read. Examples of cover letters may be requested from the ACIP Secretariat, and will be circulated when background materials are requested. The background materials can include key WG summaries, draft MMWR Policy Notes or Recommendations and Reports, key articles or studies, or a summary of key issues. "Confidential" or "draft" can be added as a header or watermark.

ACIP Presentations

WG Leads should collect meeting presentation files for meeting handouts from all presenters in your session. Approximately 2-3 weeks before each ACIP meeting the ACIP Secretariat will request presentation files for printing. The ACIP Secretariat can assist with printing needs up to one week prior to the meeting. If there are files that should go to ACIP members only (ACIP, ex-officio, liaison representatives) or voting members only, please indicate that in the file name. For any presentations that are not received electronically by one week in advance of the meeting, the WG Lead will be responsible for coordinating printing, photocopying, and delivery of hard copy per the instructions below.

- **Compile your presentations in sets** with handouts in chronological order; ready to be slipped straight into meeting binders (e.g., if you have five individual handouts, put them in sets with handouts #1, 2, 3, 4, 5 in order).
- **For ACIP membership:** 65 sets as handouts, 6 slides/page, 3 inch hole punch, collated and stapled; black/ white unless you need them to be in color (e.g., child/adolescent and adult immunization schedules).
- **For public:** 200 sets as handouts, six slides/ page, regular paper, collated and stapled.
- Delivered in labeled boxes to the Global Communications Center (Building 19) marked with ACIP meeting, name of session and session date.

Electronic presentation files will be loaded on a laptop computer in the meeting room for presentation at the ACIP meeting. Presentation files may be updated before the meeting starts, or at breaks, on meeting days, brought to us in person on a flash drive by the WG

Lead only. We cannot accommodate several people updating their files, all for the same session.

WG Leads should send the presentation files for your session to Stephanie Thomas (hkp4@cdc.gov), as a group. Please use the following naming format to ensure that the person operating the meeting computer can pull them up easily and in the proper order. For example:

- 01 HPV introduction Kempe
- 02 HPV review Markowitz
- 03 HPV proposed recommendations Meites
- 04 HPV recommendation vote Meites
- 05 HPV VFC Santoli

- Often the manufacturers provide their files to you as PDF files; if possible, we prefer PPT.

X. Evidence-Based Decision and Cost-effectiveness Analyses

CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. More information about GRADE can be found in the ACIP's GRADE handbook (https://www.cdc.gov/vaccines/acip/recs/grade/downloads/handbook.pdf).

Most issues that ACIP will vote upon require a GRADE evaluation of the evidence. However, a "when to GRADE" algorithm is currently under development and once it is finalized a link will be added here. A summary of the GRADE evidence should be included in the MMWR Policy Note, and the GRADE evidence tables are published on the ACIP website (https://www.cdc.gov/vaccines/acip/recs/grade/table-refs.html). If it is determined that a GRADE evaluation is not needed, the rationale for why GRADE is not being done should be clearly documented. The ACIP Secretariat is available to assist with questions about GRADE.

Additionally, the ACIP is currently evaluating adoption of an evidence to recommendations framework. Information about the framework will be added here when available.

The ACIP also provides guidance for the development of health economics studies (https://www.cdc.gov/vaccines/acip/committee/guidance/economic-studies.html). These procedures should be followed for economic analyses to be presented to the ACIP to ensure that economic data presented to the ACIP and its WGs are uniform in presentation, understandable, and of the highest quality.

XI. Preparing MMWR Reports

Following approval by the CDC Director, ACIP's recommendations are published in MMWR as a Policy Note whereby they become official policy. The MMWR Policy Note and Recommendations and Reports documents summarize both the ACIP recommendations (language voted upon by ACIP; e.g., the vaccine should be used for outbreak response) and guidance for use (CDC's guidance for use which is not voted upon by ACIP; e.g., how to determine when an outbreak is occurring, dose spacing, etc.).

Development of the Policy Note is led by the WG Lead. The WG Chair and other ACIP (or WG) members who meet authorship criteria should be included as co-authors on each Policy Note. The Secretariat encourages WG Leads to approach ACIP members to be included as co-authors early in the process of developing the Policy Note to allow for participation and co-authorship. The WG Lead also is responsible for developing the MMWR Recommendations and Reports (comprehensive summary of ACIP recommendations).

The WG Lead should meet with OADS prior to drafting each Policy Note and the OADS Checklist should be followed (http://intranet.cdc.gov/od/oads/osq/guide_rec/docs/CDC-Policy-Notes-Development-and-Reporting-Checklist.docx). The WG Lead should also meet with MMWR prior to developing a Recommendations and Reports document.

A Policy Note should be drafted before an ACIP vote is requested and the draft Policy Note should be distributed to ACIP members in the background materials for the session in which the vote is requested. The ACIP Secretariat will preschedule each Policy Note with MMWR to ensure prompt publication once the recommendation is approved by the CDC Director. Similarly, a Recommendations and Reports document should be drafted and distributed to ACIP members before a vote is requested.

After clearance and prior to publication, sections of the MMWR that discuss a particular product should be shared with the company making that product to ensure there are no factual errors or literature that was not included. At the time where there are proofs, the embargoed document should be shared with any pharmaceutical company that has a vaccine named in the document (with the exception of the schedule and general guidance documents). This is for awareness purposes only and edits can be made only if factual errors are identified.

XII. Termination of Work Groups

Four ACIP WGs are designated "permanent" WGs, since recurring tasks occur annually (influenza, child/adolescent immunization, adult immunization) or approximately every 3-5 years (general recommendations). The remaining WGs are designated "task-oriented," and are established when needed (Section I), and disbanded once the stated terms of reference have been completed. It is often the case that the WG has completed its terms of reference, but an ACIP recommendation statement (Policy Note or Recommendations & Reports for publication in MMWR) is still in progress. If there is not a need to have ongoing, regular WG discussion, the WG Chair and WG Lead may disband the WG, and the draft recommendations can be circulated to WG members for review and comment until a final draft is ready to put into CDC clearance.

It may happen that and ACIP WG is established and completes its TORs, and is then disbanded but at a later date new information becomes available that necessitates regrouping the WG, e.g. new safety data, a new vaccine, etc. This has occurred, for example, with the Rotavirus Vaccine WG. Therefore, a WG does not need to stay in existence "in case" a future need arises, but can be disbanded and reestablished as required, with the original WG members and/or with new WG members. When the WG Chair and WG Lead agree that it is reasonable to disband the WG, the WG Lead sends out an email to WG members thanking them for their service and contributions, and informing them of any next steps, e.g. ACIP recommendation review and publication plans.

XIII. Appendix. Annual Membership Agreement and Conflict of Interest Forms

ACIP Work Group Member Agreement

Your name:

Affiliation:

Member Type (check one): ACIP Member

Ex-Officio

Consultant

Liaison, Organization:

Please indicate the work group(s) in which you are a member:

Thank you for your generous contribution of time and expertise as a member of an Advisory Committee on Immunization Practices (ACIP) work group (WG). Serving as an ACIP WG member is an important responsibility. Work groups are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by ACIP. Work Groups review specific topics to facilitate informed and efficient decision making by ACIP voting members.

Due to the high public health significance of this work, it is imperative that all WG members understand and consent to abide by several guiding principles. Please initial each principle below to indicate that you understand it and agree to abide by it in your role as a WG member.

Nature of the advisory role. ACIP assists the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in development of public policy related to immunization of the civilian population in the United States. ACIP utilizes WGs to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs serve a key scientific role in support of vaccine policy development by ACIP, including development of policy options for presentation to ACIP and written ACIP policy statements. However, WGs do not formulate policy or vote on policy recommendations.

Participation. WGs accomplish most of their work through teleconferences; participants communicate the perspective of the organization or agency they represent, and serve as subject matter experts when appropriate. Active WGs have a set day and time for routine monthly teleconferences, which allows standing teleconferences to be

arranged and WG members to anticipate and reserve time for these teleconferences. Work group members must agree to make a best effort to attend all calls, and over the course of a year must attend at least 75% of calls.

Confidentiality. Unlike ACIP meetings, WG meetings/teleconferences are not public; data presented during these meetings are often proprietary and should not be distributed to people other than approved WG members. Only WG members and invited consultants should participate. WG proceedings should not be discussed in any personal or professional setting. Liaison representatives serving on WGs should not share proceedings, discussion, or slides with the parent organization unless permission is granted by the person who presented this information. Slides distributed at WG meetings or teleconferences should be marked as confidential and should not be shared with people who are not WG members. Work Group members should be especially sensitive about not discussing WG deliberations with anyone representing or employed by a vaccine manufacturer.

Disclosure of conflicts of interest. A participant who has a conflict of interest for a vaccine for which policy is being developed, or with the manufacturer of such a vaccine, may participate in a WG only as a consultant. Regardless of the level of financial involvement or other interest, if the participant feels unable to provide objective advice, he/she must recuse him/herself from the WG activities under consideration. The ACIP WG process relies on the integrity of each participant to disclose to the WG Chair or WG Lead any real or perceived conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal. Because ACIP WG participants are most familiar with their own situations, they must (1) to alert the WG Chair and WG Lead about any possible conflict of interest that may impact perception of impartial and fair activities of WG members and (2) to identify and certify on an annual conflict of interest screening form (a) any aspect of the work of the ACIP WG where a conflict of interest exists, and (b) that there will not be, and has not been, involvement in the efforts of the WG where participation constitutes a conflict of interest.

Please sign below to indicate that you have read and consented to abide by all guiding principles listed above.

Signature

Date

Conflict of Interest Disclosure for Participants in ACIP Work Groups

Advisory Committee for Immunization Practices (ACIP) Work Groups (WGs) serve a key scientific role in support of ACIP's vaccine policy development. A WG includes two or more ACIP members, one of whom serves as the WG Chair; a WG Lead; and other invited WG members. Other members may include ACIP liaison representatives, *ex officio* members, and invited subject matter experts.[1] WGs are convened solely to gather scientific information related to vaccines and the diseases they prevent and to analyze relevant issues and data for review and deliberation by the ACIP. WGs do not make decisions or recommendations or advise agencies. WGs report to ACIP, the parent Federal Advisory Committee. Because WGs neither vote on policy recommendations nor include a quorum of voting ACIP members, and report findings to the ACIP rather than the government, Federal Advisory Committee Act (FACA) procedural requirements do not apply to WG meetings.

Though FACA procedural requirements do not apply to ACIP WGs, CDC is sensitive to the possibility that conflicts of interest could interfere with the effective functioning of a WG. In order to avoid undue influence or the appearance of a conflict of interest in WG discussions, the WG Chair and WG Lead, with assistance from the ACIP Secretariat, screen for potential conflicts upon establishment of the WG, and request annual updates from WG members to ensure that conflicts are not present and/or have not changed. The WG Chair and WG Lead, in consultation with the ACIP Executive Secretary, may determine that a specific situation involves a conflict of interest or the appearance of one and requires that the potential participant not be involved in some or all of the ACIP WG process.

Because ACIP WG participants are most familiar with their own situations, their personal responsibilities include (1) to alert the WG Chair and WG Lead about any possible conflict of interest that may impact perception of impartial and fair activities of WG members and (2) to identify and certify on an annual conflict of interest screening form (a) any aspect of the work of the ACIP WG where a conflict of interest exists, and (b) that there will not be, and has not been, involvement in the efforts of the WG where participation constitutes a conflict of interest. The following guidance and definitions will assist in determining whether a conflict of interest exists. This guidance is not comprehensive, due to the variety of possible conflicts of interest and the potential for appearance of conflicts of interest.

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[1]Federal law (18 U.S.C. §208) prohibits Federal executive branch employees, including Special Government Employees (e.g., members of Federal advisory committees such as the ACIP), from participating in matters in which, to their knowledge, they, their spouse, domestic partner, minor child, or organization have a financial interest. WG members who are voting ACIP members or CDC employees annually file a Confidential Financial Disclosure Report [form OGE-450] with CDC's Ethics Program Activity Office. This conflict of interest questionnaire applies to WG members other than voting ACIP members or CDC employees (FTEs).

WG members should consult the WG Chair and WG Lead when there is any question about participation in WG activities. The WG lead may confer with the ACIP Executive Secretary and/or CDC legal counsel if necessary.

GUIDANCE AND DEFINITIONS

A financial conflict of interest exists when a participant has an interest in a vaccine product or pharmaceutical company that manufactures vaccines that may affect his/her imputed financial interests, or bias his/her approach to development of options for recommendations for use of that vaccine, or of a competing vaccine. A participant who has a conflict of interest for a vaccine for which policy is being developed, or with the manufacturer of such a vaccine, may participate in an ACIP WG only as a consultant with activity restricted by the WG Chair and WG Lead to that essential to provide information critical to the efforts of the WG.

A participant shall be determined to have a conflict of interest if he/she or a close relative of the participant is in a position to receive in the immediate or near term (1) a direct financial benefit of any amount deriving from recommendations for use of the vaccine under consideration; (2) a financial benefit from the vaccine manufacturer; or (3) has any other financial interest in the vaccine or manufacturer.

Regardless of the level of financial involvement or other interest, if the participant feels unable to provide objective advice, he/she must recuse him/herself from the WG activities at issue. WG members have an ongoing obligation to bring any new information regarding potential conflict(s) of interest to the attention of the WG Chair and WG Lead. In addition, WG members must inform the WG lead if they are contacted directly by a representative of a vaccine manufacturer regarding a vaccine under consideration by the WG on which they serve; the WG Lead will then inform the ACIP secretariat of any such contact.

The ACIP WG process relies on the integrity of each participant to identify to the WG Chair or WG Lead any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal. Guidelines for specific conflict of interest scenarios are presented below; please indicate "yes" or "no" next to each statement.

ACIP WORK GROUP MEMBER CONFLICT OF INTEREST QUESTIONNAIRE

Guideline	Conflict of Interest Statement	Response

1. A person will not be considered for WG membership if that person or a member of their immediate family (including a spouse, domestic partner, and/or child) is employed directly by a vaccine manufacturer or its parent company.	Are you or a member of your immediate family directly employed by a vaccine manufacturer or its parent company?	YES NO
2. A person will be not be considered for WG membership if that person is a holder of, or otherwise is entitled to royalties or other compensation for, a patent on a vaccine product or process, immunologic agent, adjuvant, or preservative that can be used for a vaccine that may come before the ACIP during the anticipated term of the concerned WG.	Are you a holder of, or otherwise entitled to royalties or other compensation for, such a patent, process, or product?	YES NO
3. To be considered for membership in an ACIP WG, a person must agree to resign any paid or unpaid[2] advisory or consulting roles to a vaccine manufacturer (except participation in clinical trials or service on data monitoring boards, which members must disclose) to perform work related to vaccines expected to be considered, and to forego such paid or unpaid consultation or membership during his/her tenure on the ACIP WG.	Do you agree to forego paid or reimbursed consultation or membership on any vaccine manufacturer advisory committees (except as noted above) and disclose participation in clinical trials and service on data monitoring boards during your tenure on the ACIP WG?	YES NO
4. WG members must agree that during their tenure on the ACIP WG, they will not serve as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer.	Do you agree that you will not serve as a paid consultant or expert witness in such litigation during your tenure on the ACIP WG?	YES NO

[2] To the extent unpaid work is performed for a manufacturer, the individual must agree to not seek or accept pay in the future for the unpaid work performed for a manufacturer during tenure on an ACIP WG.

5. Potential WG members must agree that during their tenure on the WG they will not accept honoraria or travel reimbursement directly from a vaccine manufacturer for attendance at scientific meetings or to present a lecture. They may receive travel reimbursement and/or honoraria for continuing medical education (CME) presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer and where all CME rules and regulations are followed.	Do you agree that during your tenure on the ACIP WG you will not accept honoraria or travel reimbursement directly from a vaccine manufacturer for attendance at scientific meetings or to present a lecture?[3]	YES NO
6. Except as allowed under 3, potential WG members must agree that during their tenure on the WG they will forego solicitation or acceptance of funds from vaccine manufacturers.	Do you agree that, except as allowed under 3, during your tenure on the WG you will forego solicitation or acceptance of funds from vaccine manufacturers?	YES NO
7. Federally registered lobbyists may not serve as ACIP Work Group members.	Are you a federally registered lobbyist?	YES NO

[3] Activities that do not preclude service on an ACIP Work Group include receipt of travel related reimbursement and/or honoraria for CME presentations where the source of funding may be an unrestricted grant to the CME provider by a vaccine manufacturer and that all CME rules and regulations are followed.

CERTIFICATION

All ACIP WG participants must certify that they have read these guidelines and that, to the best of his/her knowledge, he/she has disclosed all conflicts of interest that he/she may have with the vaccines under review and the manufacturers of those vaccines or of competing vaccines.

The WG Chair and WG Lead are advised to have each potential WG member review this document and complete the questionnaire upon establishment of the WG; and to request that WG members at the opening of each WG teleconference or meeting briefly state if there have been any changes in their conflict of interest information. In the event that conflicts of interest arise, the concerned member should recuse her/himself from the relevant discussion.

WG Member Name:

Affiliation:

Work Group (s):

Please initial next to the following statement:

> I certify that I have read the guidance on Conflict of Interest Disclosure for Participants of ACIP WGs, completed the questionnaire to the best of my knowledge, and disclosed any existing or potential conflicts of interest with any vaccines under review by ACIP, and with the manufacturers of those vaccines or of competing vaccines.

From: Romero, Jose
Sent: Wed, 19 Feb 2020 06:56:00 +0000
To: Aleshire, Noah (CDC/DDID/NCIRD/OD); MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: FW: Mock FDA CTGTAC/ODAC meeting - May 1 (Newark) - Availability Outreach

Noah, Jessica, and Amanda:

I have being invited to participate on a mock FDA panel for a product with a proposed indication for the (b)(4) (b)(4) Would participation on this panel be COI with my activities on the ACIP? All the information I have been provided is below. I suspect (b)(4) will be unwilling to give more details at this time. The last time I was involved in one of these panels I had to sign a nondisclosure document before I was given any material about the product and company. If you feel I should turn this down I will not be upset.

Best,

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: (b)(6)
Date: Tuesday, February 18, 2020 at 10:27 AM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: Mock FDA CTGTAC/ODAC meeting - May 1 (Newark) - Availability Outreach

Dear Dr. Romero,

(b)(4)

From: Talbot, Keipp
Sent: Thu, 17 Sep 2020 19:04:27 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: Fw: OGE 450 Report Reviewed
Attachments: Guidance Letter.pdf

Amanda,
I have CDC grants that determine both COVID and Influenza Vaccine effectiveness.
Is this new guidance:
"Therefore, for example, you may not participate in any Advisory Committee on Immunization Practices matters that involve specific grants you or your employer may have received, or would apply for, if a reasonable person would question your impartiality as a participant in those discussions. "
going to be an issue?
Keipp
From: Ethics Program Activity Tracking System (EPATS) <EPATSProdSvc@cdc.gov>
Sent: Thursday, September 17, 2020 1:31 PM
To: Keipp.talbot@vanderbilt.edu <Keipp.talbot@vanderbilt.edu>
Cc: ZGJ5@cdc.gov <ZGJ5@cdc.gov>
Subject: OGE 450 Report Reviewed

Dear Helen Talbot,

We have completed our review of your Confidential Financial Disclosure Report (OGE 450), your Foreign Activities Questionnaire, your Research Support/Project Funding Report, and the supplemental information you provided. We do appreciate your responsiveness to our request for the additional information. We don't believe that any of the disclosed interests represent a conflict of interest at the present time.

Attached is a letter that highlights areas of possible concern, and provides guidance regarding your recusal responsibilities as a member of the Advisory Committee on Immunization Practices if any matters arise regarding your research projects and discussions within the committee.

We strongly encourage you to review your OGE 450 and associated attachments in the EPATS system. In particular, your Record of Analysis provides a complete narrative of the analysis we performed to determine if any of your activities or interests could be conflicting interests.

Thank you, Helen Talbot for serving on this important committee. We value your participation!

Sincerely,

Federal Advisory Committee Management Branch

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pulbic Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date: 09/17/2020

From: Conflict of Interest Specialist
Federal Advisory Committee Management Branch

To: Helen K. Talbot
Advisory Committee on Immunization Practices

Subject: Guidance Letter, Confidential Financial Disclosure Report

1. I am writing to provide information concerning the requirements for Special Government Employees who serve on Federal Advisory Committees, in relation to conflicts of interest, or the appearance of such conflicts. Under 18 U.S.C. §208, Special Government Employees are prohibited from participating personally and substantially in any particular matter that will have a direct and predictable effect on their personal financial interests, or the financial interests of any person or organization that is imputed to them. A particular matter encompasses only matters that involve deliberation, decision, or action that is focused upon the interests of specific persons (matter involving specific parties), or a discrete and identifiable class of persons (matter of general applicability).

2. An ethics regulation, 5 C.F.R. § 2635.502, provides that a Government employee (including a SGE) may not participate in a specific party matter where a party to that matter is (or represents) an entity with which the Government employee has a "covered relationship," if such participation would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality. A Government employee is considered to have a covered relationship with an entity with which that the individual serves, or within the past year has served, as an employee. A Government employee also has a covered relationship with a member of their household (such as a spouse).

3. As a member of the Advisory Committee on Immunization Practices, you may not participate in any committee matters that would have a direct and predictable effect on your financial interests or the financial interests of others who may be imputed to you (such as a spouse or an outside employer). Additionally, you may not participate in any specific-party matters (such as discussions or recommendations involving specific grants or contracts) as a committee member, if a person/entity with which you have a covered relationship is a party to that matter. Therefore, for example, you may not participate in any Advisory Committee on Immunization Practices matters that involve specific grants you or your employer may have received, or would apply for, if a reasonable person would question your impartiality as a participant in those discussions.

4. In addition to the abovementioned statute, 18 U.S.C. §§ 203 and 205 provides that an SGE may not serve as an agent or attorney, or if compensation is received – represent, anyone before a Federal agency or Federal court on any particular matter involving specific

parties in which the individual participated personally and substantially as a SGE.

5. Lastly, an ethics regulation, 5 C.F.R. § 2635.702, provides that an employee shall not use their public office for their own private gain, or for the private gain of friends, relatives, or persons with whom the employee is affiliated in a nongovernmental capacity, including nonprofit organizations of which the employee is an officer or member, and persons with whom the employee has or seeks employment or business relations. Therefore, you may not use your official status as a member of the Advisory Committee on Immunization Practices for your own private gain or for the private gain of another.

6. If any issues of concern arise at the time of, or even before, a Committee meeting, and you are unsure whether it's a conflict, please check with Amanda C. Cohn, the Designated Federal Officer of the Committee, to determine if any action should be taken. You may contact Amanda C. Cohn or me at any time you have questions or concerns regarding the information I have provided.

Respectfully,

Duane Stone
Telephone: (770) 488-4810
Fax: (404) 471-8669

From: Bahta, Lynn (MDH)
Sent: Mon, 19 Oct 2020 19:14:05 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD); MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Subject: Requesting clarification

Hello Amanda and Jessica,
Our imm team has been invited to participate in a project out of Columbia University regarding (b)(4) (b)(4) They are including a wide range of disciplines for the project by pulling together both public and private representation (including (b)(4) and likely one or two other manufacturers – mainly from their education outreach areas). The funding is coming from Columbia U and in-kind donation of partners' time. No private sector monies are being used. Some description of the project is described below. I have been asked to be one of the leads from MDH but wanted to run this by ACIP/CDC to make sure this would not create a conflict of interest.
Hope all is well and you are staying healthy.

Deep regards,
Lynn

Lynn Bahta, R.N., MPH, CPH
Immunization Clinical Consultant | Vaccine Preventable Disease Section

Minnesota Department of Health
Office: 651-201-5505 | Mobile: (b)(6)

From: Daphne A. McCurdy (b)(6)
Sent: Wednesday, September 30, 2020 6:57 PM
To: Roddy, Margaret (MDH) <margaret.roddy@state.mn.us>
Cc: Rydrych, Diane (MDH) <diane.rydrych@state.mn.us>; Benshoof, Galen (COMM) <galen.g.benshoof@state.mn.us>; Hillary Schrenell <(b)(6)>; Lily Wendle (b)(6)
Subject: Re: FW: Connecting with Minnesota State officials working on vaccines

Diane, thank you very much for the introduction.

Margo, great to virtually meet you. I can imagine that given the pandemic you are stretched extremely thin. Thank you for everything you're doing! To answer your questions, the project will launch in early 2021 and be implemented over two years. Prior to the launch, we'd need inputs from MDH into the design of the project, which wouldn't be a significant amount of work but would require some minimal

engagement over the next two months to ensure the project is truly a partnership between the academic and practitioner leads. In addition, we'd need a letter of intent to collaborate or something similar by the end of November. Once the project launches, the initial work will focus primarily on the research that will inform the (b)(4). The part of the project where MDH would be heavily engaged probably wouldn't start until later in 2021. We envision this latter part being driven by MDH's priorities and plans for rolling out (b)(4)

Please let me know if it'd be helpful to jump on the phone and discuss in more detail. I've copied my two Columbia colleagues who can also answer additional questions about our process.

Best,
Daphne

On Wed, Sep 30, 2020 at 9:24 AM Roddy, Margaret (MDH) <margaret.roddy@state.mn.us> wrote:

Yes, exciting and important project!
I will share with a few others on the team and we will get back to you. That said, our capacity right now is stretched extremely thin. When do you see this work kicking off and can you describe the role/time commitment needed from MDH?
Best,
Margo

Margaret Roddy
Infectious Disease Epidemiology Prevention and Control

Minnesota Department of Health
Office: 651-201-5545

DEPARTMENT OF HEALTH

Thanks so much for offering to connect me with your colleagues at the Department of Health. By way of background, my organization, Columbia World Projects, is currently working with two Columbia University professors, Rishi Goyal (Director of Medicine Literature and Society Program and Assistant Professor of Medicine) and Dennis Yi Tenen (Associate Professor, English and Comparative Literature), who are (b)(4)

(b)(4)

(b)(4) As such, we would be very eager to speak with someone at Minnesota's Department of Health to explore whether there might be opportunities to work together.
Best,
Daphne

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Fri, 22 Mar 2019 10:52:58 +0000
To: Romero, Jose
Subject: Re: Please join me for HPV Vaccine Strategy Workshop at St. Jude

Agree, no conflict. Thanks!

From: Romero, Jose <RomeroJose@uams.edu>
Date: March 22, 2019 at 1:51:00 AM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: FW: Please join me for HPV Vaccine Strategy Workshop at St. Jude

Amanda:

Can I attend this meeting? I don't believe it is a COI.

JRR

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Melissa Hudson (b)(6)
Reply-To: (b)(6)
Date: Thursday, March 21, 2019 at 1:46 PM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: Please join me for HPV Vaccine Strategy Workshop at St. Jude

I'd like to invite you to an HPV Vaccine Strategy Workshop on May 6.

Dr. Romero,

I'd like to invite you to a workshop on May 6 at St. Jude Children's Research Hospital, where we are building a new multimillion-dollar initiative aimed at reducing HPV-related cancers through vaccination. Because this is a relatively new objective for St. Jude, we are hosting this workshop to discuss strategy and opportunities for impact. While starting locally, we expect to rapidly scale our activities to a national level and have secured substantial institutional funding to develop this initiative.

We would highly value your insights as a leader in the field and potential strategic partner, and would be delighted to have you join us on May 6 with other nationally recognized researchers and contributors in the field. If you are able to participate, St. Jude will cover your travel and hotel costs. Please see the meeting details below.

Please reply to let me know if you can join us. Our team will follow up to assist with travel arrangements and additional meeting information.

We are happy to answer any questions and hope you can be here for this productive day.

Best regards,
Melissa

Melissa M. Hudson, M.D., Director
Cancer Survivorship Division
Department of Oncology
St. Jude Children's Research Hospital

Meeting Details

WHEN: Monday, May 6, 2019; 8:30 a.m. - 4 p.m.

WHERE: St. Jude Children's Research Hospital, Memphis, Tennessee

WHAT: Strategy Workshop on HPV Vaccination

WHO: About 30 national and regional leaders in HPV vaccination projects, along with St. Jude leadership, faculty and staff working on the St. Jude HPV vaccination initiative, will participate in the workshop.

WHY: As the only NCI-designated Comprehensive Cancer Center dedicated solely to children, St. Jude aims to increase the number of children who benefit from the HPV vaccine and reduce their risk of preventable cancers later in life. Our goal is to establish a premier HPV prevention initiative, working closely with local, regional and national collaborators. We seek to partner with others to understand how our program can have the biggest impact.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 15 Jan 2019 03:24:13 +0000
To: Romero, Jose
Subject: Re: Proposal for Review

Jose,
This is totally fine, thank you for asking! From what it looks like below it is a company not a foreign government who is contracting with the publisher. Talk to you soon!
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Date: January 14, 2019 at 10:03:41 PM EST
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: FW: Proposal for Review

Amanda:

I would like to perform this review. It is in the area that I publish in and I have knowledge of the topic. Normally I would not bother you with this but, since the review involves research done in a foreign country (by a healthcare organization not a government) and has a small honoraria, I want to be certain it does constitute an activity that would be proscribed under the emoluments clause of COI. Please advise.

Best,

José
José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: (b)(6)
Date: Monday, January 14, 2019 at 5:08 PM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: Proposal for Review

Dear Dr. Romero,

The Scientific Peer Advisory and Review Services (SPARS) division of the American Institute of Biological Sciences (AIBS) provides peer review of grant applications and funded programs, scientific grants management, and meeting facilitation services to a diverse base of organizations, including Federal and State agencies, private research foundations, and non-government organizations https://spars.aibs.org

(b)(4)

I am contacting you to determine if you would be interested and willing to provide your expertise in the evaluation of the following proposal submission:

(b)(4)

The intent of this proposal submission is attached to aid you in your decision. Note that this has been submitted as a Letter of Intent and a full proposal submission is to follow in early February. Based on the anticipated timeline for the full proposal submission, you would have until **February 25th** to complete and submit your review to AIBS. Should you decide to participate in the review—and if no conflicts of interest exist (no collaborations with any project personnel and no affiliations with the institutions of the project personnel within the last 3 years [a list will be provided in the full proposal submission])—you are entitled to a $100 honorarium per proposal reviewed.

If you are not able to serve as a reviewer, it would be greatly appreciated if you could provide recommendations on other suitable candidates who would be interested and willing to participate in the review. **If you are willing to perform the review, please reply back to this email with an up-to-date copy of your curriculum vitae and indicate your level of expertise in reviewing the proposal submission (based on the scale below):**

High (1.0): The proposal is in your specific area of active research. Your knowledge of current publications is thorough.

Moderate (2.0): The proposal is in your general area of active research. Your knowledge of the literature is reasonably current. You could apply the techniques of the proposal with little difficulty. You have some ongoing communication with experts in the area of proposal.

I hope that you will consider participating in the review of this proposal and help support the development of this innovative program. I look forward to hearing back from you.

Best regards,

(b)(4); (b)(6)

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 9 May 2017 20:13:16 +0000
To: Lee, Grace
Subject: RE: ACIP Updates

That would great!

From: Lee, Grace [mailto:Grace.Lee@childrens.harvard.edu]
Sent: Tuesday, May 09, 2017 4:08 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Belongia, Edward A MD <Belongia.Edward@mcrf.mfldclin.edu>; Chip Walter <chip.walter@duke.edu>; David Stephens <dstep01@emory.edu>; Dr Jose Romero (RomeroJose@UAMS.edu) <RomeroJose@UAMS.edu>; Dr. Allison Kempe (Allison.Kempe@childrenscolorado.org) <Allison.Kempe@childrenscolorado.org>; Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Riley, Laura (CDC partners.org) <lriley@partners.org>; Dr. Nancy Bennett (nancy_bennett@urmc.rochester.edu) <nancy_bennett@urmc.rochester.edu>; Echezona Ezeanolue <echezona.ezeanolue@unlv.edu>; Kelly Moore <Kelly.Moore@tn.gov>; Laura McIntosh <Laura_Mcintosh@URMC.Rochester.edu>; Ms. Cynthia Pellegrini (cpellegrini@marchofdimes.com) <cpellegrini@marchofdimes.com>; Paul Hunter <phhunter@wisc.edu>; Peter Szilagyi <PSzilagyi@mednet.ucla.edu>; Robert Atmar <ratmar@bcm.edu>; Tanya Hogan (Romero) <HoganTanyaG@UAMS.edu>; Veronica Girma (Szilagyi) <VGirma@mednet.ucla.edu>
Cc: Thomas, Stephanie B. (CDC/OID/NCIRD) <hkp4@cdc.gov>
Subject: Re: ACIP Updates

Thanks Amanda,

And just for fun, my colleague Melissa Gilkey at Harvard Pilgrim Health Care Institute just launched this website with her colleagues at UNC: http://www.hpviq.org

This is a great example of the implementation work needed to complement ACIP recommendations. Hopefully over time these types of tools will expand . One day we may be able to move from" evidence to decision frameworks" to" decision to implementation frameworks".

Best
Grace

Please note: For calendar items, please contact Michelle_Regan@hphc.org.

Grace M. Lee, M.D., M.P.H.
Professor of Population Medicine
Director, Center for Healthcare Research in Pediatrics (CHeRP)
Co-Director, Population Health Sciences and Health Services Research Center
Associate Medical Director, Infection Prevention and Control
Harvard Pilgrim Health Care Institute, Boston Children's Hospital & Harvard Medical School

Address (Research):
401 Park Drive, Suite 401
Boston, MA 02215
Phone: (617) 867-4959
Fax: (617) 859-8112
www.cherp-dpm.org

www.paicap.org

Address (Clinical):
Division of Infectious Diseases
300 Longwood Avenue
Boston, MA 02115
Phone: (617) 919-2900
Fax: (617) 730-0254

From: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Sent: Tuesday, May 9, 2017 3:04 PM
To: Belongia, Edward A MD; Chip Walter; David Stephens; Dr Jose Romero (RomeroJose@UAMS.edu); Dr. Allison Kempe (Allison.Kempe@childrenscolorado.org); Reingold, Arthur MD (CDC berkeley.edu); Riley, Laura (CDC partners.org); Dr. Nancy Bennett (nancy_bennett@urmc.rochester.edu); Echezona Ezeanolue; Lee, Grace; Kelly Moore; Laura McIntosh; Ms. Cynthia Pellegrini (cpellegrini@marchofdimes.com); Paul Hunter; Peter Szilagyi; Robert Atmar; Tanya Hogan (Romero); Veronica Girma (Szilagyi)
Cc: Thomas, Stephanie B. (CDC/OID/NCIRD)
Subject: ACIP Updates

Dear ACIP members,

I hope you are all having a good Spring and are looking forward to the June ACIP meeting. I wanted to share a few updates with all of you.

1. The General Best Practices (formerly known as General Recommendations) was published on line (April 20, 2017). We are hopeful that this new format will allow for more flexible updating on a regular basis. I know there are questions about how best to evolve the General Recommnendations WG, and hopefully we can have some discussion during the administration meeting in June. Thank you to Andrew Kroger and several of you who have worked so tirelessly over the years on this update. Here is a link:

   https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

2. As I mentioned to you in February, ACIP members have been selected to being serving in July 2017, but at this time their approval is on hold. I will provide updates to you on this as soon as I have them, but our wonderful current members who are rotating off, Ally and Art, have graciously agreed to extend their participation until we have new members approved. While this is not unexpected and we always plan for not having new members approved, I want to make sure you are all aware of the situation.

3. We still do not have a person in place to fill Jean's position, and really, who can replace her? With Stephanie back from (b)(6) please reach out to her or I if you need anything. We are looking at roles and responsibilities, and how to best staff the secretariat to meet the needs of you, the work groups, and our partners.

4. We have some exciting new documents we hope to help ACIP members and WG members in response to the great feedback we have heard from you over the last year. I am incorporating some feedback from the WG leads within CDC and then will share with you these documents for input before they are finalized. There are still some missing pieces, but these will be living documents that we can update as needed.

5. Below are some links to articles you may be interested in reading. The JAMA issue focuses on Conflicts of Interest and a few articles pertain to ACIP.

Please feel free to reach out if you need anything. Plan on dinner if you are free for the Wed of ACIP, we will likely return to General Muir unless any of you have other suggestions!

Best,
Amanda

- There are some articles focused on vaccines in Science Magazine:

  http://science.sciencemag.org/content/356/6336

- There is JAMA issue focused on COI:.

  From: JAMA [mailto:updates@jamanetwork.org]
  Sent: Tuesday, May 2, 2017 4:31 PM
  To: Posner, Sam (CDC/OID/NCIRD) <shp5@cdc.gov>
  Subject: JAMA Conflict of Interest Theme Issue - May 2, 2017: Volume 317, Number 17

Read the latest research from JAMA, which provides readers throughout the world with essential medical information and a unique forum for discussions shaping the future of medical practice and public health.

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http://click.alerts.jamanetwork.com/click/g06tr-as4n9q-62v1s6s4/

New Issue

May 2, 2017; Volume 317, Number 17

In This Issue of JAMA

Highlights

JAMA. 2017;317(17):1707 doi:10.1001/jama.2016.13108

Viewpoint

Conflict of Interest: Why Does It Matter?

Harvey V. Fineberg, MD, PhD

JAMA. 2017;317(17):1717 doi:10.1001/jama.2017.1869

Payments to Physicians: Does the Amount of Money Make a Difference?

Bernard Lo, MD; Deborah Grady, MD, MPH

JAMA. 2017;317(17):1719 doi:10.1001/jama.2017.1872

Why There Are No "Potential" Conflicts of Interest

Matthew S. McCoy, PhD; Ezekiel J. Emanuel, MD, PhD

JAMA. 2017;317(17):1721 doi:10.1001/jama.2017.2308

Addressing Bias and Conflict of Interest Among Biomedical Researchers

Lisa Bero, PhD

JAMA. 2017;317(17):1723 doi:10.1001/jama.2017.3854

Conflict of Interest and the Integrity of the Medical Profession

Allen S. Lichter, MD

JAMA. 2017;317(17):1725 doi:10.1001/jama.2017.3191

Strategies for Addressing a Broader Definition of Conflicts of Interest

Ross E. McKinney Jr, MD; Heather H. Pierce, JD, MPH

JAMA. 2017;317(17):1727 doi:10.1001/jama.2017.3857

Role of Leaders in Fostering Meaningful Collaborations Between Academic Medical Centers and Industry While Also Managing Individual and Institutional Conflicts of Interest

Philip A. Pizzo, MD; Thomas J. Lawley, MD; Arthur H. Rubenstein, MBBCH

JAMA. 2017;317(17):1729 doi:10.1001/jama.2017.2573

Conflict of Interest Among Medical School Faculty: Achieving a Coherent and Objective Approach

Jeffrey S. Flier, MD

JAMA. 2017;317(17):1731 doi:10.1001/jama.2017.1751

Teaching Medical Students About Conflicts of Interest

Diane B. Wayne, MD; Marianne Green, MD; Eric G. Neilson, MD

JAMA. 2017;317(17):1733 doi:10.1001/jama.2017.2079

Funding, Institutional Conflicts of Interest, and Schools of Public Health: Realities and Solutions

Sandro Galea, MD, DrPH; Richard Saitz, MD, MPH

JAMA. 2017;317(17):1735 doi:10.1001/jama.2017.1659

Conflicts of Interest and Professional Medical Associations: Progress and Remaining Challenges

Steven E. Nissen, MD

JAMA. 2017;317(17):1737 doi:10.1001/jama.2017.2516

Conflict of Interest in Practice Guidelines Panels

Harold C. Sox, MD

JAMA. 2017;317(17):1739 doi:10.1001/jama.2017.2701

Financial Conflicts of Interest in Continuing Medical Education: Implications and Accountability

Barbara Barnes, MD, MS

JAMA. 2017;317(17):1741 doi:10.1001/jama.2017.2981

Challenges and Opportunities in Disclosing Financial Interests to Patients

Katrina Armstrong, MD; Andrew A. Freiberg, MD

JAMA. 2017;317(17):1743 doi:10.1001/jama.2017.2656

Business Model–Related Conflict of Interests in Medicine: Problems and Potential Solutions

Ian Larkin, PhD; George Loewenstein, PhD

JAMA. 2017;317(17):1745 doi:10.1001/jama.2017.2275

What Do Patients Think About Physicians' Conflicts of Interest? Watching Transparency Evolve

Abigail Zuger, MD

JAMA. 2017;317(17):1747 doi:10.1001/jama.2017.2995

Public Disclosure of Payments to Physicians From Industry

Charles Ornstein, BA

JAMA. 2017;317(17):1749 doi:10.1001/jama.2017.2613

Managing Conflicts of Interest in Industry-Sponsored Clinical Research: More Physician Engagement Is Required

Joanne Waldstreicher, MD; Michael E. Johns, MD

JAMA. 2017;317(17):1751 doi:10.1001/jama.2017.4160

Physicians, Industry Payments for Food and Beverages, and Drug Prescribing

Robert Steinbrook, MD

JAMA. 2017;317(17):1753 doi:10.1001/jama.2017.2477

Conflict of Interest and the Role of the Food Industry in Nutrition Research

Dariush Mozaffarian, MD, DrPH

JAMA. 2017;317(17):1755 doi:10.1001/jama.2017.3456

How Should Journals Handle the Conflict of Interest of Their Editors? Who Watches the "Watchers"?

Julie D. Gottlieb, MA; Neil M. Bressler, MD

JAMA. 2017;317(17):1757 doi:10.1001/jama.2017.2207

Medical Journals, Publishers, and Conflict of Interest

Thomas J. Easley

JAMA. 2017;317(17):1759 doi:10.1001/jama.2017.3421

Conflict of Interest and Legal Issues for Investigators and Authors

Joseph P. Thornton, JD

JAMA. 2017;317(17):1761 doi:10.1001/jama.2017.4235

A Piece of My Mind

After the Medical Error

Miranda Worthen, MPhil, PhD

JAMA. 2017;317(17):1763 doi:10.1001/jama.2017.0004

Editorial

The Complex and Multifaceted Aspects of Conflicts of Interest

William W. Stead, MD

JAMA. 2017;317(17):1765 doi:10.1001/jama.2017.3435

Conflict of Interest and Medical Journals

Phil Fontanarosa, MD, MBA; Howard Bauchner, MD

JAMA. 2017;317(17):1768 doi:10.1001/jama.2017.4563

Reconsidering Physician–Pharmaceutical Industry Relationships

Colette DeJong, BA; R. Adams Dudley, MD, MBA

JAMA. 2017;317(17):1772 doi:10.1001/jama.2017.4455

Original Investigation

Types and Distribution of Payments From Industry to Physicians in 2015

Kathryn R. Tringale, BS; Deborah Marshall, MAS, MD; Tim K. Mackey, PhD; et al

JAMA. 2017;317(17):1774 doi:10.1001/jama.2017.3091

Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing

Ian Larkin, PhD; Desmond Ang, MS; Jonathan Steinhart, MA; et al

JAMA. 2017;317(17):1785 doi:10.1001/jama.2017.4039

Editorial: **Time to Reconsider Physician–Pharmaceutical Industry Relationships**;
Colette DeJong, BA; R. Adams Dudley, MD, MBA

JAMA Professionalism

Is There a Conflict of Interest?

Shiphra Ginsburg, MD, MEd, PhD; Wendy Levinson, MD

JAMA. 2017;317(17):1796 doi:10.1001/jama.2017.2233

Research Letter

Characteristics and Dissemination of Phase 1 Trials Approved by a UK Regional Office in 2012

Ayodele Odutayo, MD; Bethan Copsey, MMath; Susan Dutton, MSc; et al

JAMA. 2017;317(17):1799 doi:10.1001/jama.2017.1471

Comment & Response

Reassessment of an Asthma Diagnosis

Vipul V. Jain, MD, MS; William Stringer, MD

JAMA. 2017;317(17):1801 doi:10.1001/jama.2017.3501

Reassessment of an Asthma Diagnosis

Lawrence W. Raymond, MD, ScM

JAMA. 2017;317(17):1801 doi:10.1001/jama.2017.3498

Physician Charges and Medicare Payments

Jeffrey Plagenhoef, MD

JAMA. 2017;317(17):1802 doi:10.1001/jama.2017.3758

Countering Public Health Threats

Rebecca Voelker, MSJ

JAMA. 2017;317(17):1716 doi:10.1001/jama.2017.4846

Immunotherapy for Rare Skin Cancer

Rebecca Voelker, MSJ

JAMA. 2017;317(17):1716 doi:10.1001/jama.2017.4278

New Addition to Parkinson Therapy

Rebecca Voelker, MSJ

JAMA. 2017;317(17):1716 doi:10.1001/jama.2017.4468

Poetry and Medicine

The Meeting

Charles McMahon, MD

JAMA. 2017;317(17):1805 doi:10.1001/jama.2016.20120

JAMA Revisited

Do Moral Principles Change?

JAMA. 2017;317(17):1806 doi:10.1001/jama.2017.0647

JAMA Patient Page

Conflict of Interest in Medicine

Christopher C. Muth, MD

JAMA. 2017;317(17):1812 doi:10.1001/jama.2017.4044

JAMA Masthead

JAMA

JAMA. 2017;317(17):1711 doi:10.1001/jama.2016.13109

You Also May Like

http://click.alerts.jamanetwork.com/click/g06tr-as4nbb-62v1s6s0/

JAMA Professionalism: Is There a Conflict of Interest?

Amanda Cohn, MD
CDR, US Public Health Service
Executive Secretary
Advisory Committee on Immunization Practices
NCIRD/CDC
Office: 404-639-6039
Cell: (b)(6)
Email: acohn@cdc.gov

Centers for Disease Control and Prevention (CDC) Roybal Campus
1600 Clifton Road MS A-87

Atlanta, GA 30329-4027

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 4 Sep 2018 19:45:59 +0000
To: Talbot, Helen K
Subject: RE: ACIP Work Group forms: Please complete ASAP

Keipp-

You are on my list of people to reach out to this week, so good timing! I just wanted to check and make sure you are still open for the October ACIP meeting? I still believe the new members will be approved by then, although I could certainly be wrong! I am trying to get word back in the next week, but wanted to make sure you still had that on your radar.

Thanks!
Amanda

From: Talbot, Helen K <keipp.talbot@vumc.org>
Sent: Tuesday, September 4, 2018 3:41 PM
To: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: RE: ACIP Work Group forms: Please complete ASAP

Jessica,

Perfect timing!
I just finished mine and was about to reply to your last email.
I have attached my forms.
I listed my only potential conflict for the pneumococcal work group but then attached a complete list – just in case!!!!!
Please let me know if you have any questions.

Keipp

From: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>
Sent: Tuesday, September 04, 2018 2:25 PM
To: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>
Cc: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/OID/NCIRD) <aji8@cdc.gov>
Subject: ACIP Work Group forms: Please complete ASAP

Hello,

A friendly reminder to please complete your ACIP Work Group Agreement and Conflict of Interest Forms ASAP. If you have already completed your forms and believe you have received this message in error, just let us know and we will confirm that we have your forms on file.

Also, please do not hesitate to reach out to us if you have any questions or concerns.

Thank you,
Jessica

From: Advisory Committee on Immunization Practices (CDC)
Sent: Monday, August 20, 2018 10:10 AM
To: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>
Cc: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/OID/NCIRD) <aji8@cdc.gov>
Subject: ACIP Work Group forms: Please complete by 8/29/18

Hello everyone,

The ACIP Secretariat has made a few updates to the document outlining how ACIP Work Groups should function (attached). This document was first distributed last year, and is again being shared with all ACIP Work Group members. The key changes for this year include:

1. An updated ACIP Work Group conflict of interest policy (page 6-9), key changes include:
    1. Making it more explicit that the guidance applies to the vaccines or related products under the purview of each ACIP WG on which a person serves (and the companies that manufacture those products)
    2. People who serve as a principal/co-principal investigator, or site principal investigator for an industry sponsored clinical trial (even when funding goes to the institution/program) cannot serve on the WG

3. WG members are not allowed to provide uncompensated advice to companies during their tenure on the WG (or within the prior 6 months when joining).

2. Addition of an appendix (page 28-31) providing more explicit guidance on the roles and responsibilities of the FDA, ISO, and ISD representatives on ACIP WGs.

We value your expertise immensely, and we understand that this change in our conflict of interest policy may result in some members having to come off certain Work Groups. However we felt that these changes were necessary at this time to avoid an appearance or perception of a conflict of interest in Work Group discussions.

Additionally, the ACIP Secretariat is again coordinating collection of the Work Group conflict of interest and Work Group membership agreement form. Fillable pdf versions of both forms are attached. **Please complete and sign both the conflict of interest and membership agreement forms and return them to acip@cdc.gov by 8/29/2018.** On your response, please also cc: the Work Group Leads for each Work Group you serve on.

Finally, thank you for your participation on an ACIP Work Group! We value your time, expertise, and participation in the ACIP process. Please do not hesitate to let us know if you have any questions or concerns.

Thank you,

Jessica MacNeil and Amanda Cohn

Jessica MacNeil, MPH
Epidemiologist

Deputy Executive Secretary, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS C-25
Atlanta, GA 30329-4027
Phone: (404) 639-1194

Cell: (b)(6)

Fax: (404) 315-4681

Email: jmacneil@cdc.gov

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Sat, 16 Sep 2017 20:00:50 +0000
To: Bernstein, Henry
Subject: RE: ACIP Work Group forms: please complete by 9/15/2017

Sorry I did not respond earlier this week! Yes, just say you are a consultant for now. Hopefully all will be resolved soon :)

-----Original Message-----
From: Bernstein, Henry [mailto:Hbernstein@northwell.edu]
Sent: Tuesday, September 12, 2017 11:19 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: FW: ACIP Work Group forms: please complete by 9/15/2017

Hi, Amanda!

What member type should I check off? I am assuming I am not officially an ACIP member yet, right?

Thanks,
Hank

_____
From: Advisory Committee on Immunization Practices (CDC) [acip@cdc.gov]
Sent: Monday, September 11, 2017 4:21 AM
To: Advisory Committee on Immunization Practices (CDC)
Subject: [EXTERNAL] ACIP Work Group forms: please complete by 9/15/2017

External Email. Use Caution.

Hello everyone,

The ACIP Secretariat has developed a new document outlining guidance for how ACIP Work Groups should function (attached). This is part of our continuous efforts to improve transparency and consistency among ACIP Work Groups. This document is being shared with all ACIP Work Group members.

Additionally, this year the ACIP Secretariat is coordinating collection of the Work Group conflict of interest forms. This will hopefully remove some of the administrative burden from the CDC Work Group Leads, and allow Work Group members who participate in multiple ACIP Work Groups to complete the forms a single time. This year we are also implementing a Work Group membership agreement form. Fillable pdf versions of both forms are attached. Please complete and sign both the conflict of interest and membership agreement forms and return them to acip@cdc.gov<mailto:acip@cdc.gov> by 9/15/2017.

Finally, thank you for your participation on an ACIP Work Group! We value your time, expertise, and participation in the ACIP process. Please do not hesitate to let us know if you have any questions or concerns.

Thank you,

Jessica MacNeil and Amanda Cohn

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Fri, 21 Dec 2018 18:39:05 +0000
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Kevin Ault
Subject: RE: ACIP Work Groups

Agreed. Thanks!

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Sent: Wednesday, December 19, 2018 2:46 PM
To: Kevin Ault <kault2@kumc.edu>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: RE: ACIP Work Groups

Hi Kevin,

Yes, I believe we discussed and decided this was ok. Amanda, please let us know if you feel differently.

Thanks,
Jessica

From: Kevin Ault <kault2@kumc.edu>
Sent: Tuesday, December 18, 2018 1:11 PM
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: RE: ACIP Work Groups

I think I am all set did we decide if I have an HPV COI? I am involved in an HPV therapeutics trial - http://ir.inovio.com/news-and-media/news/press-release-details/2017/Inovio-Begins-Phase-3-Clinical-Trial-of-VGX-3100-for-the-Treatment-of-HPV-Related-Cervical-Pre-Cancer/default.aspx and http://www.hpvreveal1.com/ - Kevin Ault

---

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) [mailto:aji8@cdc.gov]
Sent: Thursday, December 13, 2018 7:26 AM
To: Kevin Ault <kault2@kumc.edu>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: ACIP Work Groups

Hello Kevin,

I wanted to touch base with you regarding ACIP Work Group assignments. I know when we talked a couple of weeks ago you were interested in staying on the Influenza Work Group and were also interested in joining the HPV Work Group and Adult Work Group. Is that correct? We of course would love to have you on all three Work Groups, but please let me know if you think that is too much and we can probably prioritize a couple. We can also always adjust later if needed.

If that sounds good to you, please let me know, and I can get you in touch with Lauri and David who lead the Work Groups.

Thanks,
Jessica

P.S. The HPV Work Group meets on varying Fridays from 2-3pm Eastern and the Adult Work Group meets on the 3rd Monday from 3-4pm Eastern.

From: Romero, Jose
Sent: Fri, 26 Apr 2019 13:41:20 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: Re: ACIP

Amanda:
I am sorry to hear that he has decided to step down. I had hoped that he would be able to "divest" himself of his conflicting studies but, his vaccine research is such a integral part of his career that he just can't. I respect him for making such a hard decision. It is for the best although his expertise will be missed. I also means more work for you and Jessica as you try to fill that gap.
Sorry also to hear that your time is being consumed by measles on top of all the other things you have. Let me know what I can do to help.
José
PS: I'll see if you have time to talk next week. -JRR
José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute
Sent from iPhone, please excuse brevity, grammatical, and typographical errors.

On Apr 26, 2019, at 08:25, Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov> wrote:

Jose and Grace,
I am sad about this, but have an enormous amount of respect for Stefan's very thoughtful decision. I'll respond and cc you, but maybe over the weekend as I am drowning with measles :).
We will also start working on next steps.
Amanda

From: Stefan Gravenstein <stefan_gravenstein@brown.edu>
Date: April 26, 2019 at 9:11:12 AM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: ACIP

Amanda,

Thank you for enduring me for the brief tenure on the ACIP. I've cycled through mentors and colleagues (and cc'd you on a few of the communications) to get advice on which path to follow regarding maintaining a viable and credible voice on the ACIP. You saw how I presented the information, and hope you agree that my depiction of the

COI issues was fair to the CDC's and your process and perspective. I have so much respect for the work of the CDC and ACIP in particular, that I also don't want to create perception or evidence of a COI through my work with the ACIP and you. The recommendations I received were uniform, whether from folks vested in my work (their own or institutional COIs) and those without evident conflict. They felt the relative value I present to the ACIP, although unique, is eclipsed by the potential value and impact of the other work that I do which presents the very conflict that concerns my ACIP appointment; I should step down.

So, as agonizing as this choice is for me, I'd like to do whatever it is I need to do to step down from the ACIP (b)(6) (b)(6) (b)(6) Please tell me what I need to do next and if there's anything else I need to do to preserve the integrity of the ACIP.

Thank you again for your sincere efforts to find space for someone like me on the ACIP. I am,

Gratefully yours,

Stefan

Stefan Gravenstein, MD, MPH
Professor of Medicine and Health Services Policy and Practice
Brown University

From: Lee, Grace
Sent: Fri, 26 Apr 2019 14:40:21 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Cc: Romero, Jose
Subject: Re: ACIP

Dear Amanda and Jose
It sounds like he really struggled with this for a while. I respect his decision- it's a tough one.
Best
Grace

—
Grace M. Lee, MD MPH
Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health
Professor of Pediatrics, Stanford University School of Medicine
Please send calendar requests to:
Lisa Perry, Executive Assistant
Liperry@stanfordchildrens.org
(650) 724-3664 (office)
Sent from my iPhone

On Apr 26, 2019, at 9:25 AM, Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov> wrote:

Jose and Grace,
I am sad about this, but have an enormous amount of respect for Stefan's very thoughtful decision. I'll respond and cc you, but maybe over the weekend as I am drowning with measles :).
We will also start working on next steps.
Amanda

From: Stefan Gravenstein <stefan_gravenstein@brown.edu>
Date: April 26, 2019 at 9:11:12 AM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: ACIP

Amanda,

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Thank you again for your sincere efforts to find space for someone like me on the ACIP. I am,

Gratefully yours,

Stefan

Stefan Gravenstein, MD, MPH
Professor of Medicine and Health Services Policy and Practice
Brown University

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 25 Jul 2017 03:32:44 +0000
To: Bernstein, Henry
Subject: RE: COI question

Hmmm, I'm not sure about the last part. I'll check on that. It's always good for me to make sure we are more clear.

I am so sorry about the delays, I am getting the sense that it will be a few weeks before things start moving, I'll keep you in the loop as best I can. I can't imagine how frustrating it is!

Amanda

-----Original Message-----
From: Bernstein, Henry [mailto:Hbernstein@northwell.edu]
Sent: Friday, July 21, 2017 2:02 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: RE: COI question

Thanks for the quick response, Amanda.

(1) We'll go with the 1 month cutoff, if it's still up in the air next week.

(2) Definitely excited about moving forward when you hear something about ACIP.

(3) Lastly, just confirming my interpretation of the COI info that it's fine to accept travel expenses and an honorarium since it's an unrestricted educational grant, right? The second part of the last bullet (copied here) says "with the exception that they may receive travel reimbursements..." etc but it doesn't explicitly mention honoraria again.

Members do not accept honoraria or travel reimbursement with a funding source from a vaccine manufacturer for attendance at scientific meetings, with the exception that they may receive travel reimbursement for CME presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer.

Warm regards,
Hank

_____
From: Cohn, Amanda (CDC/OID/NCIRD) [anc0@cdc.gov]
Sent: Friday, July 21, 2017 1:13 PM
To: Bernstein, Henry
Subject: [EXTERNAL] RE: COI question

You are not bothering me at all! I checked back in with Mark, he may not respond until Monday. My guess is they can't decide.

I am also hoping that things start to free up with hiring in the next couple of weeks, I will let you know as soon as I hear something!

With regards to this, you can do thinks with an unrestricted educational grant. See last bullet below
:) Best, Amanda

Conflicts of Interest when Participating as a Member Upon appointment each voting member is required to file an Office of Government Ethics 450 form (OGE450 https://urldefense.proofpoint.com/v2/url?u=http-3A__www.oge.gov_Forms-2DLibrary_OGE-2DForm-2D450-2D-2DConfidential-2DFinancial-2DDisclosure-2DReport_&d=DwIFAg&c=vq5m7Kktb9l80A_wDJ5D-g&r=8sixPnbjSw5nrGDgvuvhJQasDsz0Jn5FM8eDRlhF4Ug&m=EOIH0zZOzxKFG0oAzwPOQqZRSt6NRyOVnHZOySUxklk&s=_dzjAUhlgg2zUOEluvpx5ik4Bx3oNA5P33KGid_VhNs&e=), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC. Confidential Financial Disclosure must be updated annually during a member's term. At every ACIP meeting the Chair calls for conflict of interest disclosure from each voting member, at the opening of the meeting and prior to any vote taken by the ACIP. Any actual or perceived conflict of interests will be explored fully by the Secretariat, CDC's Federal Advisory Committee Management Branch, and CDC legal counsel if necessary. Members with declared interests will be asked to recuse themselves from participating in the discussion and decision-making of the issues relating to that interest. A member who has any doubt as to whether he/she has an interest that should be declared, or whether he/she should take part in the proceedings, should ask the Secretariat for guidance.
As detailed below and in the Appendix, ACIP members will have consented to the following requirements as a condition of membership.

* No member, their spouse, or a member of their immediate family can be directly employed by a vaccine manufacturer or its parent company.
* Members cannot hold stock in any vaccine manufacturer or its parent company in excess of the OGE de minimus amounts. Members also agree that they, their spouse and minor children will not purchase such stock during their tenure on the committee.
* Members cannot be holders of or otherwise be entitled to royalties or other compensation for a patent on a vaccine product or process, immunologic agent, adjunct or preservative that can be used for a vaccine that may come before the ACIP during the anticipated term of appointment under consideration.
* Members agree to resign any advisory or consulting roles, whether paid or unpaid, to a vaccine manufacturer (except participation in clinical trials or service on data monitoring boards) and to forego such consultation or membership on any vaccine manufacturer advisory committees (except participation in clinical trials or service on data monitoring boards), during his/her tenure on the ACIP.
* Members forego solicitation or acceptance of funds from vaccine manufacturers on behalf of themselves or others.
* During their tenure on the ACIP, members do not serve as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer.
* Members do not accept honoraria or travel reimbursement with a funding source from a vaccine manufacturer for attendance at scientific meetings, with the exception that they may receive travel reimbursement for CME presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer.

-----Original Message-----
From: Bernstein, Henry [mailto:Hbernstein@northwell.edu]
Sent: Friday, July 21, 2017 12:46 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: COI question

Amanda -

Sorry to bug you, but I wanted to get your take on something.

Steve Pelton, chief of Peds ID at Boston Medical Center, has asked me to be a part of a national CME program on meningococcal disease and vaccination. This program is through their BU School of Medicine CME office, which receives *unrestricted* educational grants (eg, from Pfizer) to do so. We make all of our own slides and industry has no input at all in this initiative. BU School of Medicine CME office will pay travel expenses to give the presentations and there is an honorarium, but I have no idea how much (and I didn't even ask).

Would my participation be considered a conflict of interest as an incoming ACIP member?

Thanks,

Hank

The information contained in this electronic e-mail transmission and any attachments are intended only for the use of the individual or entity to whom or to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this communication is not the intended recipient, or the employee or agent responsible for delivering this communication to the intended recipient, you are hereby notified that any dissemination, distribution, copying or disclosure of this communication and any attachment is strictly prohibited. If you have received this transmission in error, please notify the sender immediately by telephone and electronic mail, and delete the original communication and any attachment from any computer, server or other electronic recording or storage device or medium. Receipt by anyone other than the intended recipient is not a waiver of any attorney-client, physician-patient or other privilege.

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 25 Jul 2017 16:44:04 +0000
To: Bernstein, Henry
Subject: RE: COI question

ACIP members may accept honoraria for CME presentation as long as the source is an unrestricted grant to the CME provider.

Best,
Amanda

-----Original Message-----
From: Bernstein, Henry [mailto:Hbernstein@northwell.edu]
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Thanks,

Hank

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From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Thu, 15 Feb 2018 15:36:11 +0000
To: Bernstein, Henry
Cc: Frantz, Jennifer; bonniem@standford.edu; byington@tamhsc.edu
Subject: RE: COID

Hi Hank,

I don't think it's appropriate for you to be participating on the call because of perceptions about conflict of interest. In situations in the past where any ACIP member has been on liaison calls before a vote, it has been the WG Chair, but typically it is the CDC SME and the AAP liaison to the WG only. I did hear from Jen that Flor is unable to join the call. Carrie and Bonnie, if you would like for us to invite Chip Walter, the Flu WG Chair, to the call we can do that.

Carrie and Bonnie, Nancy Messonnier would like to join the call in the beginning to explain why we are asking ACIP to consider a vote at this upcoming meeting. Would that be ok with you? Also, Lisa is working to get slides to you guys as soon as possible.

Best,
Amanda

-----Original Message-----
From: Bernstein, Henry [mailto:Hbernstein@northwell.edu]
Sent: Thursday, February 15, 2018 8:55 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Cc: (b)(6)
Subject: RE: COID

Good morning!

ACIP is my priority now and I definitely understand the sensitivity around vote discussions, given my expansion of responsibility from AAP/COID representative on the influenza workgroup to ACIP member. I do sincerely appreciate your efforts in helping guide me in keeping a transparent balance going forward.

With that in mind, I wasn't envisioning any formal vote discussions or decision-making with COID on the call tomorrow, since COID/AAP hasn't had an opportunity to review and discuss this topic as a group in any detail. In particular, I thought tomorrow's call with COID leadership was one of information-dispensing to them by Lisa rather than sharing any detail around confidential influenza workgroup discussions about an ACIP vote.

Since harmonization with the CDC has always been an important goal for the AAP, my participation on the call might help share/clarify perspective and answer questions about the science with respect to the pediatric population and therefore, would not be perceived as/considered a conflict.

Of course, if you still feel it's best for me not to join tomorrow's call, I will not call in.

Thanks,
Hank

From: Cohn, Amanda (CDC/OID/NCIRD) [anc0@cdc.gov]
Sent: Wednesday, February 14, 2018 4:02 PM
To: Bernstein, Henry
Cc: Frantz, Jennifer
Subject: [EXTERNAL] COID

External Email. Use Caution.
Hi Hank,

I just touched base with Jen about making sure you are not included on rosters/emails about COID discussions related to ACIP votes. I think after ACIP we can have further discussion about how to make sure you can continue to provide all the amazing work you do for COID around communicating around flu vaccine issues while ensuring there are no appearances of conflicts. Thanks so much, and look forward to seeing you next week!

Amanda

From: Romero, Jose
Sent: Thu, 1 Aug 2019 20:13:52 +0000
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Aleshire, Noah (CDC/DDID/NCIRD/OD)
Subject: Re: COI?

Thank you.

JRR

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

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Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Jessica MacNeil <aji8@cdc.gov>
Date: Thursday, August 1, 2019 at 8:18 AM
To: "Romero, Jose" <RomeroJose@uams.edu>, "Cohn, Amanda (CDC/DDID/NCIRD/OD)" <anc0@cdc.gov>, Noah Aleshire <uwo2@cdc.gov>
Subject: Re: COI?

Hi Jose,

Noah and I just discussed this and agreed that this does not represent a COI for you.

Thanks,
Jessica

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Wednesday, July 31, 2019 11:56 AM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)

<aji8@cdc.gov>; Aleshire, Noah (CDC/DDID/NCIRD/OD) <uwo2@cdc.gov>
Subject: COI?

Amada et al:

Hope you are all well.

My section offers a yearly ID Update for the pediatrician. It is CME acreditted by the University. The meeting has been suspended because of a lack of faculty and accompanying increased clinical demands. We are planning on bringing it back in 2020. Funding for the meeting is in part from pharma companies that pay for advertising space at the meeting. So my question is, is this a COI for me if I have nothing to do with the planning of the meeting? I assign it to the faculty member.

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu


Please consider the environment before printing this email.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 25 Jun 2019 12:42:40 +0000
To: Sharon Frey
Cc: Romero, Jose; Aleshire, Noah (CDC/DDID/NCIRD/OD)
Subject: RE: conflict of interest question - please respond

Sharon,

I am so sorry, (b)(6) and missed this when I returned back. I am cc'ing Noah who is helping sort through COI issues, you could have done this, but please feel free to pester us in the future if you don't hear back!

Look forward to seeing you tomorrow!

Amanda

From: Sharon Frey <sharon.frey@health.slu.edu>
Sent: Thursday, June 20, 2019 3:37 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Romero, Jose <RomeroJose@uams.edu>; Sharon Frey <sharon.frey@health.slu.edu>
Subject: Re: conflict of interest question - please respond

Hi,

Since I have not heard from anyone, I have given up the ship and gave (b)(4) (b)(4)

See you soon.
Sharon E. Frey, M.D.
Ralph Kinsella Endowed Chair in Internal Medicine
Professor and Associate Director of Clinical Research
Clinical Director, Center for Vaccine Development
Division of Infectious Diseases, Allergy and Immunology
Saint Louis University Medical School
1100 S. Grand Blvd (DRC- Rm 827)
St. Louis, MO 63104
ph: 314-977-5500
fax: 314-771-3816

From: Sharon Frey
Sent: Tuesday, June 4, 2019 2:18 PM
To: Amanda m Cohn (CDC/OID/NCIRD)
Cc: Romero, Jose
Subject: conflict of interest question - please respond

Hi Amanda,

This information is confidentia (b)(4)

(b)(4)

(b)(4) Would either of these options exclude me from voting on ACIP? Neither performing (b)(4) would influence my votes in any way but I know COI can be about appearances. If not possible, I would provide the (b)(4)

Please advise.

Thanks,

Sharon

Sharon E. Frey, M.D.
Ralph Kinsella Endowed Chair in Internal Medicine
Professor and Associate Director of Clinical Research
Clinical Director, Center for Vaccine Development
Division of Infectious Diseases, Allergy and Immunology

Saint Louis University Medical School
1100 S. Grand Blvd (DRC- Rm 827)
St. Louis, MO 63104
ph: 314-977-5500
fax: 314-771-3816

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Thu, 8 Oct 2020 15:18:19 +0000
To: Kevin Ault; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Subject: RE: conflict of interest

We do not need a paper trail, thank you!

From: Kevin Ault <kault2@kumc.edu>
Sent: Thursday, October 8, 2020 11:17 AM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Subject: conflict of interest

I was an investigator on a phase I / II clinical trial for an HPV treatment that was sponsored by Janssen. We ended our participation in the trial in mid-March 2020 due to poor recruiting and the pandemic. I have a paper trial if you need any records from me. Kevin Ault

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Thu, 24 Aug 2017 18:59:10 +0000
To: Bennett, Nancy M.; Reingold, Arthur MD (CDC berkeley.edu)
Cc: Belongia, Edward A MD; Chip Walter; David Stephens; Dr Jose Romero (RomeroJose@UAMS.edu); Dr. Allison Kempe (Allison.Kempe@childrenscolorado.org); Riley, Laura (CDC partners.org); Echezona Ezeanolue; Grace Lee; Kelly Moore; McIntosh, Laura; Ms. Cynthia Pellegrini (cpellegrini@marchofdimes.com); Paul Hunter; Peter Szilagyi; Robert Atmar; Tanya Hogan (Romero); Veronica Girma (Szilagyi); MacNeil, Jessica R. (CDC/OID/NCIRD); Thomas, Stephanie B. (CDC/OID/NCIRD)
Subject: RE: final version

Yes, completely agree as well and we will start putting in the group of permanent WGs.

Thanks!
Amanda

From: Bennett, Nancy M. [mailto:Nancy_Bennett@URMC.Rochester.edu]
Sent: Thursday, August 24, 2017 2:42 PM
To: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>
Cc: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Belongia, Edward A MD <Belongia.Edward@mcrf.mfldclin.edu>; Chip Walter <chip.walter@duke.edu>; David Stephens <dstep01@emory.edu>; Dr Jose Romero (RomeroJose@UAMS.edu) <RomeroJose@UAMS.edu>; Dr. Allison Kempe (Allison.Kempe@childrenscolorado.org) <Allison.Kempe@childrenscolorado.org>; Riley, Laura (CDC partners.org) <lriley@partners.org>; Echezona Ezeanolue <echezona.ezeanolue@unlv.edu>; Grace Lee <grace.lee@childrens.harvard.edu>; Kelly Moore <Kelly.Moore@tn.gov>; McIntosh, Laura <Laura_Mcintosh@URMC.Rochester.edu>; Ms. Cynthia Pellegrini (cpellegrini@marchofdimes.com) <cpellegrini@marchofdimes.com>; Paul Hunter <phhunter@wisc.edu>; Peter Szilagyi <PSzilagyi@mednet.ucla.edu>; Robert Atmar <ratmar@bcm.edu>; Tanya Hogan (Romero) <HoganTanyaG@UAMS.edu>; Veronica Girma (Szilagyi) <VGirma@mednet.ucla.edu>; MacNeil, Jessica R. (CDC/OID/NCIRD) <aji8@cdc.gov>; Thomas, Stephanie B. (CDC/OID/NCIRD) <hkp4@cdc.gov>
Subject: Re: final version

I actually think this is a good question and like the idea of having it be a permanent group. (b)(5)
(b)(5)
(b)(5) Thanks Art for that suggestion and I support it. Best. Nana

Nancy M. Bennett, MD, MS
Professor of Medicine and Public Health Science
Director, Center for Community Health
Co-director, Clinical and Translational Science Institute
University of Rochester School of Medicine and Dentistry

Sent from my iPhone

On Aug 23, 2017, at 12:14 PM, Art Reingold <reingold@berkeley.edu> wrote:

Amanda
i have now had a chance to read the most recent version of the WG guidance and want to congratulate you/other CDC staff-it is well-wriitten, clear, and very helpful.

(b)(5)

(b)(5) Just a thought for your consideration. art

On Aug 21, 2017, at 6:36 AM, Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov> wrote:

Hi Everyone,

Hope you are doing well. Attached is the finalized WG guidance incorporating your comments. We are going to be officially implementing this guidance over the next couple of weeks. The ACIP Secretariat will be sending out WG member agreements and COIs to all WG members and we will be collecting all forms, so that WG members on multiple WGs only have to sign one agreement.

As ACIP members, you will not need to complete the COI form, but we will ask you to complete the WG agreement, which is a fillable PDF. Please let me know if you have any questions,

Best,

Amanda

Amanda Cohn, MD
CAPT, US Public Health Service
Executive Secretary, Advisory Committee on Immunization Practices
National Center for Immunization and Respiratory Diseases
Phone: (404) 639-6039
Email: acohn@cdc.gov

<Work Group Guidance__Aug 2017.docx>

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Thu, 24 Aug 2017 13:20:00 +0000
To: Hunter, Paul; Reingold, Arthur MD (CDC berkeley.edu); Grace Lee
Subject: RE: final version

I completely agree with you all. (b)(5) (b)(5) Thanks for picking that up!

Amanda

From: Hunter, Paul [mailto:PHUNTE@milwaukee.gov]
Sent: Thursday, August 24, 2017 7:57 AM
To: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Grace Lee (b)(6)
Subject: Re: final version

Dear Amanda,

As I mentioned in the message I wrote before not attending the Evidence Based Work Group earlier this week, I also see an ongoing role for the work group in advising and assisting the ACIP Secretariat in education of work group members and modifying protocols in response to their suggestions about Evidence to Recommendations and Considerations for Implementation.

Paul Hunter MD
www.linkedin.com/in/paulhuntermd
841 N Broadway St #315, Milwaukee WI 53202
414-286-0924, phunte@milwaukee.gov

Please excuse autocorrect errors due to mobile phone software.

On Aug 23, 2017, at 11:15 AM, Art Reingold <reingold@berkeley.edu> wrote:

Amanda
i have now had a chance to read the most recent version of the WG guidance and want to congratulate you/other CDC staff-it is well-wriitten, clear, and very helpful.

(b)(5)

(b)(5) Just a thought for your consideration. art

On Aug 21, 2017, at 6:36 AM, Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov> wrote:

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Hope you are doing well. Attached is the finalized WG guidance incorporating your comments. We are going to be officially implementing this guidance over the next couple of weeks. The ACIP Secretariat will be sending out WG member agreements and COIs to all WG members and we will be collecting all forms, so that WG members on multiple WGs only have to sign one agreement.

As ACIP members, you will not need to complete the COI form, but we will ask you to complete the WG agreement, which is a fillable PDF. Please let me know if you have any questions,

Best,

Amanda

Amanda Cohn, MD
CAPT, US Public Health Service
Executive Secretary, Advisory Committee on Immunization Practices
National Center for Immunization and Respiratory Diseases
Phone: (404) 639-6039
Email: acohn@cdc.gov

<Work Group Guidance__Aug 2017.docx>

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Thu, 31 May 2018 13:39:59 +0000
To: Romero, Jose
Subject: RE: GLG Project Opportunity: (b)(4)

(b)(5)

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Thursday, May 31, 2018 9:38 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Re: GLG Project Opportunity: (b)(4)

Thanks for such a quick response. (b)(5)

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute
Sent from iPhone, please excuse brevity, grammatical, and typographical errors.

On May 31, 2018, at 08:34, Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov> wrote:

(b)(5)

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Thursday, May 31, 2018 9:29 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Fwd: GLG Project Opportunity: (b)(4)

Amanda:

I am checking to see if I can do the below. (b)(5) Is accepting the offer below a COI.

Best,

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases

Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute
Sent from iPhone, please excuse brevity, grammatical, and typographical errors.

Begin forwarded message:

From: (b)(6)
Date: May 30, 2018 at 10:42:40 CDT
To: Jose Romero <romerojose@uams.edu>
Subject: GLG Project Opportunity: (b)(4)

Hi Dr. Romero,

I hope you're doing well. I'm writing to introduce the below opportunity on (b)(4) (b)(4) My client is hoping to speak with pediatricians who see high patient volumes with (b)(4) Given your background, I thought you might be able to add value here.

Please let me know by accepting the opportunity at the following link:

(b)(4)

This call is expected to occur between June 4th to June 8th.
- Please note that you will need access to a computer during this consultation.

PLEASE NOTE THAT THE CLIENT INTENDS TO RECORD THIS PHONE CALL. BY ACCEPTING THIS PROJECT, YOU AGREE TO BE RECORDED.

PLEASE NOTE: This consultation will be conducted in a double-blinded fashion. If you do accept, please do not identify yourself if/when the call occurs. If you disclose your identity during the call, GLG may be required to report to the client the fee received by the Council

Member for participating on this call as required by a client's compliance policies or by various HCP state, federal and international transparency reporting laws and regulations such as the US Physician Payment Sunshine Act.

Typically, GLG clients are identified by name so that you can determine whether you might have an obligation or conflict that prevents you from consulting for them. In this case, the client has asked that this project be conducted in double-blinded fashion such that both your identity and the client's entity name remain confidential, although the type of client is identified. If you or organizations you work with require more information about this client to determine whether you have a conflict that may impact your participation in this project, please either contact a GLG Research Manager or decline the project.

Please note that this client is subject to certain fair market value (FMV) constraints for its engagements with healthcare professionals. As a result, the rate offered for this project may be less than your standard hourly fee.

As a reminder, Doctors who are participating in ongoing clinical trials are NOT permitted to discuss confidential trial data regarding the on-going trial, the experience of patients enrolled in the trial, or trial enrollment data or trends before such information has been made public. Depending on the agreements and public disclosure, doctors are likely to be able to discuss trial design, already released data and the mechanism of action.
Doctors serving on a committee for a clinical trial or drug - such as any Clinical Trial Steering Committee, Clinical Trial Monitoring Committee, Data Safety Monitoring Board or Clinical Trial (Scientific) Advisory Board - MAY NOT discuss that trial or the drug in active trial.
Doctors serving on a company's scientific advisory board (SAB) (vs. a trial-specific advisory board) MAY NOT discuss any of that company's ongoing clinical trials.

Thanks,

(b)(6); (b)(4)

This Client has elected to record this phone consultation. By accepting this consultation, you consent to being recorded.

Terms and Conditions: If you have not already done so, you will be required to complete an online tutorial about confidentiality and sign the current Terms and Conditions of Council Membership ("Terms and Conditions"), before you can accept this project. We may also ask you a few questions to help determine your suitability for this project. Acceptance is complete once you acknowledge that your GLG profile is current and that your participation in the project is bound by the Terms and Conditions, which provide, among other things if you are employed, you may not speak on behalf of or about your employer. To encourage you to err on the side of caution during your participation as a Council Member, you may submit a payment request for the full time you set aside for any project you discontinue in order to comply with your obligations and the Terms and Conditions.

Confidentiality: Please remember you must not disclose confidential information to GLG or its clients and you must not mention your other GLG projects with any client or other third party. This includes the topic of past discussions, identity of clients you have worked with, and frequency of work you do with us. Feel free to contact us directly with any questions. Certain of our

clients may wish to screen the topic and your ability to consult comfortably prior to a second conversation with a research analyst. Please note that you may receive such a call from a client compliance staff member and may invoice us for your time spent on both calls.

Compensation: Council Members are compensated at their regular honorarium rate for the time spent on the phone with our client, unless otherwise specified by GLG. Any requests for preparation time must be authorized by GLG. GLG does not guarantee that if you accept this project, the client will contact you.

ref: ci.PQ7g1J

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Thu, 30 May 2019 12:00:01 +0000
To: Romero, Jose; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Subject: Re: Kelly

Hi Jose,
So sorry, that was one of the updates we meant to give you but we should have sent an email! This is a new HHS rule that they are not doing waivers to extend people. It's one of those things where other committees took advantage of that and now we have lost the ability to do it when we need it.
Yes, Noah and Jessica are working on a much more extensive process to make sure this does not happen again, we will review this all before we nominate candidates. I will say I did have this conversation with (b)(6) but I learned a lot as there were some clear things I did not communicate, such as investigator initiated studies are still conflicts!
I am out of the office from tomorrow through next week, I (b)(6) (b)(6) (b)(6) (b)(6)
Take care,
Amanda
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Date: May 30, 2019 at 2:15:49 AM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>, MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Subject: Kelly

Amanda and Jessica:

During behind the scene emails while on the Hepatitis WG call yesterday I learned that (b)(6) will not be allowed to serve another year on ACIP (a little embarrassing since when we last spoke I thought that was "a done deal"). Have you given any thought about who we should bring on and how long the vetting process will take?

One of the things I wanted to discuss with you at our monthly call (mea culpa for missing it) was that we need to be very (more) explicit about the need of the candidates to divest themselves of all ties with companies that could pose a COI. I know you discuss this with them but in order avoid a similar situation as that with Stephan.

José
José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and

Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Romero, Jose
Sent: Wed, 19 Feb 2020 20:18:30 +0000
To: Aleshire, Noah (CDC/DDID/NCIRD/OD); MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: Re: (b)(4) study closings

Very good.

JRR

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Noah Aleshire <uwo2@cdc.gov>
Date: Wednesday, February 19, 2020 at 2:13 PM
To: "Romero, Jose" <RomeroJose@uams.edu>, Jessica MacNeil <aji8@cdc.gov>, "Cohn, Amanda (CDC/DDID/NCIRD/OD)" <anc0@cdc.gov>
Subject: RE: (b)(4) study closings

Hi Jose,

If at all possible, I recommend finding a different signatory for the invoices. Your signature as a PI on an invoice as described could create the appearance of a conflict of interest.

Let me know if there are no other individuals at your institution who can sign, and we can see what we can figure out.

Thanks,

Noah

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Wednesday, February 19, 2020 2:52 PM
To: Aleshire, Noah (CDC/DDID/NCIRD/OD) <uwo2@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: FW (b)(4) study closings
Importance: High

Noah:

I am sorry to keep bothering you this week.

When I joined the ACIP I transferred all my (b)(4) clinical trials to one of my junior faculty. She left the institution in August of last year. The research institute is closing all the trials down but, there are invoices related to these studies that need to be sent to (b)(4) for work previously performed (The invoice in reference was for Chart Review/Data Mining fee for 32 hours.) I am being asked if I can sign the invoices in place of the departed PI because I was her Section Chief (I had no involvement in the trial after transfer to her). All payments are to the Arkansas Children's Research Institute, not me. Can I do this?

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: (b)(6)
Date: Wednesday, February 19, 2020 at 12:36 PM
To: "Romero, Jose" <RomeroJose@uams.edu>
Cc: " (b)(6)
(b)(6)
Subject: (b)(4) study closings

Dr. Romero,
With us in the process of closing the (b)(4) we are running into issues with (b)(6) (b)(6) no longer being here.

1. We have an invoice in the workday process that is pending (b)(6) approval. Central IRB invoice
2. We are needing PI signature for invoices related to invoice items.

Would it be possible for us to amend the PI to you for Item #1 so that we can push this invoice approval to you?
And what suggestion do you have regarding item #2

(b)(6); (b)(4)

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 18 Sep 2018 20:09:07 +0000
To: Romero, Jose; Lee, Grace
Subject: Re: National Academies (b)(4)

Hi! I totally agree with Jose :)
Thank you for checking!
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Date: September 18, 2018 at 2:10:39 PM EDT
To: Lee, Grace <GMLee@stanfordchildrens.org>
Cc: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Re: National Academies pilot (b)(4)

Grace:
Amanda has the final say on this of course, however I do not think It poses a issue nor COI so long as it is not presented as a view of the ACIP.
Let's see what AC has to say.
Best,
José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute
Sent from iPhone, please excuse brevity, grammatical, and typographical errors.

On Sep 18, 2018, at 13:02, Lee, Grace <GMLee@stanfordchildrens.org> wrote:

Dear Amanda and Jose,
See below for interesting email on vaccine safety. Do you think it causes a conflict for ACIP? I'd like to do it if possible.
Thanks much
Grace

From: (b)(6)
Date: Thursday, September 13, 2018 at 5:42 AM
To: "Lee, Grace" <GMLee@stanfordchildrens.org>
Subject: RE: National Academies pilot (b)(4)

Hi Dr. Lee,

Yes, that's not a problem. Please send it along to the ACIP to see what she says.

Thanks,

(b)(6)

From: Lee, Grace <GMLee@stanfordchildrens.org>
Sent: Thursday, September 13, 2018 2:06 AM
To (b)(6)
Subject: Re: National Academies pilot (b)(4)

Dear (b)(6)
This sounds quite interesting! I'm happy to join the discussion. The only thing is that I might have to clear it with the ACIP secretariat since I'm still on ACIP. Do you mind if I send this to her quickly and confirm that there's no problem to me joining?
Thanks much
Grace

--
Grace M. Lee, MD MPH
Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health
Professor of Pediatrics, Stanford University School of Medicine
300 Pasteur Drive, G-306B
Stanford, CA 94305
(650) 497-0618 (office)
(b)(6) *(cell)*

Please send calendar requests to:
Lisa Perry, Executive Assistant
Liperry@stanfordchildrens.org
(650) 724-3664 (office)

From: (b)(6)
Date: Tuesday, September 11, 2018 at 11:52 AM

To: "Lee, Grace" <GMLee@stanfordchildrens.org>
Subject: National Academies pilot (b)(4)

Dear Dr. Lee,

I am a study director at the National Academies of Sciences, Engineering, and Medicine. I am working on a pilot (b)(4) which the National Academies is undertaking in conjunction with (b)(4)

(b)(4)

Would you be willing to be part of the small expert group for the topic (b)(4) If so, I will set up a call for you and the other experts to talk to the science writer. The writer will then draft an article and may come back to you for any follow up information. When the draft article is complete, it will be reviewed internally by the National Academies before being posted on the web.

I'd be happy to talk to you further about this budding activity if that would be helpful. Thank you for considering this request.

Best regards,

(b)(6)

From: Cohn, Amanda (CDC/DDID/NCIRD)
Sent: Thu, 1 Nov 2018 20:13:15 +0000
To: Sharon Frey
Subject: RE: new study at SLU for which I will be a site PI

Thanks Sharon! Completely agree this is not a conflict, but still appreciate the awareness.

Best,
Amanda

From: Sharon Frey <sharon.frey@health.slu.edu>
Sent: Thursday, November 1, 2018 3:12 PM
To: Cohn, Amanda (CDC/DDID/NCIRD) <anc0@cdc.gov>
Cc: Sharon Frey <sharon.frey@health.slu.edu>
Subject: new study at SLU for which I will be a site PI

Amanda,

I will be the local site PI on a clinical MVA study at SLU which will be sponsored directly by (b)(4) (b)(4) The money will go to SLU and I will be paid from those funds. We are not reviewing (b)(4) (b)(4) at this time but wanted you to be aware. If there is someone else I need to report to please let me know. I do not consider this a COI and was not sure if I needed to report it.

Regrds,

Sharon

From: Cohn, Amanda (CDC/DDID/NCIRD)
Sent: Tue, 16 Oct 2018 11:07:02 +0000
To: Romero, Jose; Hills, Susan (CDC/DDID/NCEZID)
Cc: Fischer, Marc (CDC/DDID/NCEZID); MacNeil, Jessica R. (CDC/DDID/NCIRD); (b)(6)
Subject: Re: NY Ctr for Travel & Trop Med letter

Hi all,
Just to clarify, (b)(5)

(b)(5)

He will be at the pre-ACIP training and we can ask him about it directly.
Thanks,
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Date: October 16, 2018 at 1:46:19 AM EDT
To: Hills, Susan (CDC/DDID/NCEZID) <hri1@cdc.gov>, Cohn, Amanda (CDC/DDID/NCIRD) <anc0@cdc.gov>
Cc: Fischer, Marc (CDC/DDID/NCEZID) <mxf2@cdc.gov>, MacNeil, Jessica R. (CDC/DDID/NCIRD) <aji8@cdc.gov>, (b)(6) >, (b)(6) >
Subject: Re: NY Ctr for Travel & Trop Med letter

Susan:

I agree with your comments and concerns.

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: "Hills, Susan (CDC/DDID/NCEZID)" <hri1@cdc.gov>
Date: Monday, October 15, 2018 at 12:55 PM
To: "Cohn, Amanda (CDC/DDID/NCIRD)" <anc0@cdc.gov>, "Romero, Jose" <RomeroJose@uams.edu>
Cc: "Fischer, Marc (CDC/DDID/NCEZID)" <mxf2@cdc.gov>, "MacNeil, Jessica R. (CDC/DDID/NCIRD)" <aji8@cdc.gov>, '(b)(6)', (b)(6)
Subject: FW: NY Ctr for Travel & Trop Med letter

Amanda and Jose
Thanks for forwarding this additional letter from this group. One concern to highlight with the letter and with Dr Connor possibly making a comment at ACIP is that his affiliation with the manufacturer is not made clear. It might be useful to ask him to note any affiliations if he speaks at the meeting. Dr Connor does note as a competing interest that he has attended advisory board meetings sponsored by the manufacturer when he publishes journal articles. (In a similar way, I understand the manufacturer has paid for Dr Halstead to attend and make comment at previous ACIP meetings but Dr Halstead also did not note this when speaking).
Thanks
Susan

From: Cohn, Amanda (CDC/DDID/NCIRD)
Sent: Monday, October 15, 2018 11:26 AM
To: Thomas, Stephanie B. (CDC/DDID/NCIRD) <hkp4@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD) <aji8@cdc.gov>
Cc: Fischer, Marc (CDC/DDID/NCEZID) <mxf2@cdc.gov>; Hills, Susan (CDC/DDID/NCEZID) <hri1@cdc.gov>
Subject: FW: NY Car for Travel & Trop Med letter

Stephanie- For inclusion in the meeting minutes. Thanks!

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Monday, October 15, 2018 1:23 PM
To: Cohn, Amanda (CDC/DDID/NCIRD) <anc0@cdc.gov>
Subject: NY Car for Travel & Trop Med letter

Amanda:

I received a letter from Dr. Connor of the New York Center for Travel and Tropical Medicine dated 10/4/18 regarding (b)(4) A cc has been sent to you. I briefly skimmed the letter. Attached is a scanned copy of the letter for you review. Do we need to talk

about this? Also, I do not see that the letter was sent to the Subject Matter Expert or the Chair of the JE WG. Should they receive a copy.

Best,

José
José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
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Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu


Please consider the environment before printing this email.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Mon, 5 Oct 2020 02:03:41 +0000
To: Talbot, Keipp
Subject: RE: OGE 450 Report Reviewed

Sorry for taking a while to respond to this Keipp. But you are fine with your VE grants, it is the clinical trial language that this was referring to primarily. All CDC grants are not product specific so it's all good.

Hope you are doing ok!
Amanda

From: Talbot, Keipp <keipp.talbot@vumc.org>
Sent: Thursday, September 17, 2020 3:04 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: Fw: OGE 450 Report Reviewed

Amanda,

I have CDC grants that determine both COVID and Influenza Vaccine effectiveness.

Is this new guidance:
"Therefore, for example, you may not participate in any Advisory Committee on Immunization Practices matters that involve specific grants you or your employer may have received, or would apply for, if a reasonable person would question your impartiality as a participant in those discussions. "
going to be an issue?

Keipp

From: Ethics Program Activity Tracking System (EPATS) <EPATSProdSvc@cdc.gov>
Sent: Thursday, September 17, 2020 1:31 PM
To: Keipp.talbot@vanderbilt.edu <Keipp.talbot@vanderbilt.edu>
Cc: ZGJ5@cdc.gov <ZGJ5@cdc.gov>
Subject: OGE 450 Report Reviewed

Dear Helen Talbot,

We have completed our review of your Confidential Financial Disclosure Report (OGE 450), your Foreign Activities Questionnaire, your Research Support/Project Funding Report, and the supplemental information you provided. We do appreciate your responsiveness to our request for the additional information. We don't believe that any of the disclosed interests represent a conflict of interest at the present time.

Attached is a letter that highlights areas of possible concern, and provides guidance regarding your recusal responsibilities as a member of the Advisory Committee on Immunization Practices if any matters arise regarding your research projects and discussions within the committee.

We strongly encourage you to review your OGE 450 and associated attachments in the EPATS system. In particular, your Record of Analysis provides a complete narrative of the analysis we performed to determine if any of your activities or interests could be conflicting interests.

Thank you, Helen Talbot for serving on this important committee. We value your participation!

Sincerely,

Federal Advisory Committee Management Branch
[**WARNING** : This email came from an external source. Please treat this message with additional caution.]

From: Bahta, Lynn (MDH)
Sent: Wed, 21 Oct 2020 18:54:25 +0000
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: Requesting clarification

Thanks for the response. I too, have concerns about the perceived COI. I would appreciate the OGC feedback as it may impact whether or not MDH gets involved in this project.
Thanks again.
Lynn

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Sent: Wednesday, October 21, 2020 8:33 AM
To: Bahta, Lynn (MDH) <lynn.bahta@state.mn.us>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: RE: Requesting clarification

Hello Lynn,

Thanks for reaching out about this. Amanda and I have been going back and forth a bit about this activity. Likely it is fine, but we are a bit concerned about whether this might be perceived as a COI with the increased scrutiny on ACIP around COVID-19 vaccines.

Would you like me to reach out to our Office of General Counsel to get their feedback? Or, Amanda – have you had any further thoughts on this since we last talked?

Thanks,
Jessica

From: Bahta, Lynn (MDH) <lynn.bahta@state.mn.us>
Sent: Monday, October 19, 2020 3:14 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Subject: Requesting clarification

Hello Amanda and Jessica,
Our imm team has been invited to participate in a project out of Columbia University regarding (b)(4) (b)(4) They are including a wide range of disciplines for the project by pulling together both public and private representation (including (b)(4) and likely one or two other manufacturers – mainly from their education outreach areas). The funding is coming from Columbia U and in-kind

donation of partners' time. No private sector monies are being used. Some description of the project is described below. I have been asked to be one of the leads from MDH but wanted to run this by ACIP/CDC to make sure this would not create a conflict of interest.
Hope all is well and you are staying healthy.

Deep regards,
Lynn

Lynn Bahta, R.N., MPH, CPH
Immunization Clinical Consultant | Vaccine Preventable Disease Section

Minnesota Department of Health
Office: 651-201-5505 | Mobile (b)(6)

DEPARTMENT OF HEALTH

From: Daphne A. McCurdy <(b)(6)
Sent: Wednesday, September 30, 2020 6:57 PM
To: Roddy, Margaret (MDH) <margaret.roddy@state.mn.us>
Cc: Rydrych, Diane (MDH) <diane.rydrych@state.mn.us>; Benshoof, Galen (COMM) <galen.g.benshoof@state.mn.us>; Hillary Schrenell <(b)(6); Lily Wendle <(b)(6)>
Subject: Re: FW: Connecting with Minnesota State officials working on vaccines

Diane, thank you very much for the introduction.

Margo, great to virtually meet you. I can imagine that given the pandemic you are stretched extremely thin. Thank you for everything you're doing! To answer your questions, the project will launch in early 2021 and be implemented over two years. Prior to the launch, we'd need inputs from MDH into the design of the project, which wouldn't be a significant amount of work but would require some minimal engagement over the next two months to ensure the project is truly a partnership between the academic and practitioner leads. In addition, we'd need a letter of intent to collaborate or something similar by the end of November. Once the project launches, the initial work will focus primarily on the research that will inform the (b)(4) The part of the project where MDH would be heavily engaged probably wouldn't start until later in 2021. We envision this latter part being driven by MDH's priorities and plans for rolling out (b)(4)

Please let me know if it'd be helpful to jump on the phone and discuss in more detail. I've copied my two Columbia colleagues who can also answer additional questions about our process.

Best,
Daphne

On Wed, Sep 30, 2020 at 9:24 AM Roddy, Margaret (MDH) <margaret.roddy@state.mn.us> wrote:

Yes, exciting and important project!
I will share with a few others on the team and we will get back to you. That said, our capacity right now is stretched extremely thin. When do you see this work kicking off and can you describe the role/time commitment needed from MDH?
Best,
Margo

Margaret Roddy
Infectious Disease Epidemiology Prevention and Control

Minnesota Department of Health
Office: 651-201-5545

DEPARTMENT OF HEALTH

Thanks so much for offering to connect me with your colleagues at the Department of Health. By way of background, my organization, Columbia World Projects, is currently working with two Columbia University professors, Rishi Goyal (Director of Medicine Literature and Society Program and Assistant Professor of Medicine) and Dennis Yi Tenen (Associate Professor, English and Comparative Literature), who are (b)(4)

(b)(4)

(b)(4)

s such, we would be very eager to speak with someone at Minnesota's Department of Health to explore whether there might be opportunities to work together.
Best,
Daphne

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Fri, 15 Mar 2019 02:07:02 +0000
To: Kevin Ault; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Cc: 'Romero, Jose'
Subject: RE: RSV DSMB

Kevin,
You can talk to her about vaccines without going through us, but if she wants to interview you as an acip member about an acip deliberation or decision, please reach out to us first. Does that make sense?
Thanks!
Amanda

From: Kevin Ault <kault2@kumc.edu>
Date: March 14, 2019 at 6:32:55 PM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>, MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Cc: 'Romero, Jose' <RomeroJose@uams.edu>
Subject: RE: RSV DSMB

I have another question for you. I have done a number of interviews over the years with Tara Haelle, a health journalist. Can I talk to her about vaccines or do I need to go through the CDC communications people? Kevin Ault

---

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [mailto:anc0@cdc.gov]
Sent: Monday, March 11, 2019 8:26 PM
To: Kevin Ault <kault2@kumc.edu>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Cc: 'Romero, Jose' <RomeroJose@uams.edu>
Subject: RE: RSV DSMB

Kevin- Thanks for the update! You can just update at the next timepoint when we ask for an update. Since the final meeting is April 8th, you would no longer be considered to have a conflict 6 months from then (October)

From: Kevin Ault <kault2@kumc.edu>
Sent: Monday, March 11, 2019 10:09 AM
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: 'Romero, Jose' <RomeroJose@uams.edu>
Subject: RSV DSMB

I wanted to update you on this COI item. For the past several years I have been on a data and safety monitoring committee for a maternal immunization clinical trial. This clinical trial involves a RSV

vaccine. We have scheduled our final DSMB meeting for April 8th. If you have any questions let me know, and if I need to update my COI information likewise please forward to me. Kevin Ault

---

From: Kevin Ault
Sent: Tuesday, November 13, 2018 11:29 AM
To: 'MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)' <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Romero, Jose <RomeroJose@uams.edu>
Subject: RE: Great seeing you all

12-3 would certainly work, I think Dr. Romero and I are on central time.

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) [mailto:aji8@cdc.gov]
Sent: Tuesday, November 13, 2018 11:17 AM
To: Kevin Ault <kault2@kumc.edu>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Romero, Jose <RomeroJose@uams.edu>
Subject: RE: Great seeing you all

Hi Kevin,

I wanted to try to schedule a time for all of us to touch base. Would sometime during the afternoon on 11/26 or 12/3 work for you?

Thanks
Jessica

From: Kevin Ault <kault2@kumc.edu>
Sent: Thursday, November 8, 2018 7:43 PM
To: Cohn, Amanda (CDC/DDID/NCIRD) <anc0@cdc.gov>; Romero, Jose <RomeroJose@uams.edu>
Cc: MacNeil, Jessica R. (CDC/DDID/NCIRD) <aji8@cdc.gov>
Subject: RE: Great seeing you all

yes let's talk. There are many RSV vaccines in development, maybe in four years, one will make to an ACIP vote. I want to be sure I am getting this right. Kevin Ault

---

From: Cohn, Amanda (CDC/DDID/NCIRD) [anc0@cdc.gov]
Sent: Thursday, November 08, 2018 12:07 PM
To: Romero, Jose; Kevin Ault
Cc: MacNeil, Jessica R. (CDC/DDID/NCIRD)
Subject: RE: Great seeing you all

Hi Kevin,

This is a COI that we would write an exemption for if you prefer to stay on it. But you will not be able to deliberate or vote on anything related to (b)(4) if a vote comes up. You also are not able to be on that

WG. That has happened in the past and is ok from my perspective, given that there are not multiple vaccines this company makes so it is only RSV that is an issue. It is totally up to you.

Happy to touch base over the phone!

Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Tuesday, November 6, 2018 11:34 PM
To: Kevin Ault <kault2@kumc.edu>; Cohn, Amanda (CDC/DDID/NCIRD) <anc0@cdc.gov>
Subject: Re: Great seeing you all

Kevin:

I believe this will fall under COI. This is something that needs to be discussed with Amanda (and possibly Duane). I am ccing her on this response.

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Kevin Ault <kault2@kumc.edu>
Date: Monday, November 5, 2018 at 5:16 PM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: RE: Great seeing you all

Another longer term issue is that I am on a DSMB for (b)(4) RSV vaccine trial. The DSMB was actually put together by a third party. The trial is fully enrolled. Maternal immunization is an interest of mine. This would appear to be a COI based on our orientation. I think we should discuss if I

should resign from this board in anticipation of RSV vaccines being on future ACIP agendas. Kevin Ault (latest publicly available data below)

http://ir.novavax.com/news-releases/news-release-details/novavax-reaches-significant-enrollment-milestone-preparetm-phase

---

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 17 Jul 2018 19:55:47 +0000
To: Romero, Jose
Cc: Stone, Duane (CDC/OCOO/OCIO/MASO)
Subject: RE: Save The Date: August 25th (b)(4) (b)(4)

Hi Jose,

Duane and I spoke and we agree that given that this is not a vaccine manufacturer, and additionally we already have vaccine recommendations for persons using this medication. I do not believe this poses a conflict of interest in relation to your work in ACIP.

Thanks,
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Tuesday, July 17, 2018 11:17 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Re: Save The Date: August 25th (b)(4) (b)(4)

Amanda:

I hate to add to your load but, I would appreciate you asking. Alternatively, if you tell me who I should call I can speak to them. For COI I have been working with Duane Stone.

Best,

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
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Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute

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Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

Please consider the environment before printing this email.

From: "Cohn, Amanda (CDC/OID/NCIRD)" <anc0@cdc.gov>
Date: Tuesday, July 17, 2018 at 9:37 AM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: RE: Save The Date: August 25th - (b)(4) (b)(4)

Hi Jose,

This is a good question, I'm not sure. Do you want me to review this with others at CDC and get back to you?

Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Monday, July 16, 2018 11:09 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: FW: Save The Date: August 25th (b)(4) (b)(4)

Amanda:

Am I allowed to do this?

Jose

From: (b)(6); (b)(4)]
Sent: Monday, July 16, 2018 9:30 AM
To: Romero, Jose
Cc: (b)(6)
Subject: Save The Date: August 25th - (b)(4) (b)(4)

Dear Dr. Romero:

On behalf of (b)(4) we would like to cordially invite you to the (b)(4) - (b)(4) (b)(4) You will receive a formal invitation in the coming weeks from (b)(4) where you will be able to register to attend. In the meanwhile, we would appreciate it if you could reply this e-mail to let us know of your interest and availability. If you are available, please add this meeting to your calendar and we will follow up with an invitation and then issue you a consultant agreement before booking your travel. Thank you.

(b)(4); (b)(6)

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 17 Jul 2018 15:35:46 +0000
To: Romero, Jose
Subject: RE: Save The Date: August 25th (b)(4) (b)(4)

It's totally fine! It may be better to have a phone conversation with Duane ☺

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Tuesday, July 17, 2018 11:17 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Re: Save The Date: August 25th (b)(4) (b)(4)

Amanda:

I hate to add to your load but, I would appreciate you asking. Alternatively, if you tell me who I should call I can speak to them. For COI I have been working with Duane Stone.

Best,

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
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Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: "Cohn, Amanda (CDC/OID/NCIRD)" <anc0@cdc.gov>
Date: Tuesday, July 17, 2018 at 9:37 AM
To: "Romero, Jose" <RomeroJose@uams.edu>

Subject: RE: Save The Date: August 25th - (b)(4) (b)(4)

Hi Jose,

This is a good question, I'm not sure. Do you want me to review this with others at CDC and get back to you?

Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Monday, July 16, 2018 11:09 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: FW: Save The Date: August 25th - (b)(4) (b)(4)

Amanda:

Am I allowed to do this?

Jose

From: Brandon Wan [mailto (b)(6)
Sent: Monday, July 16, 2018 9:30 AM
To: Romero, Jose
Cc: (b)(6)
Subject: Save The Date: August 25th (b)(4) (b)(4)

Dear Dr. Romero:

On behalf of (b)(4) we would like to cordially invite you to the (b)(4) (b)(4) (b)(4) You will receive a formal invitation in the coming weeks from (b)(4) where you will be able to register to attend. In the meanwhile, we would appreciate it if you could reply this e-mail to let us know of your interest and availability. If you are available, please add this meeting to your calendar and we will follow up with an invitation and then issue you a consultant agreement before booking your travel. Thank you.

(b)(4)

(b)(4); (b)(6)

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 17 Jul 2018 20:08:50 +0000
To: Romero, Jose
Cc: Stone, Duane (CDC/OCOO/OCIO/MASO)
Subject: RE: Save The Date: August 25th (b)(4) (b)(4)

Sorry for the incomplete sentence!

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Tuesday, July 17, 2018 4:01 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Cc: Stone, Duane (CDC/OCOO/OCIO/MASO) <zgj5@cdc.gov>
Subject: Re: Save The Date: August 25th - (b)(4) (b)(4)

Thank you both for taking the time to review and offer your opinions. I appreciate it.

José
José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Research Institute
Sent from iPhone, please excuse brevity, grammatical, and typographical errors.

On Jul 17, 2018, at 14:55, Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov> wrote:

Hi Jose,

Duane and I spoke and we agree that given that this is not a vaccine manufacturer, and additionally we already have vaccine recommendations for persons using this medication. I do not believe this poses a conflict of interest in relation to your work in ACIP.

Thanks,
Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Tuesday, July 17, 2018 11:17 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Re: Save The Date: August 25th (b)(4) (b)(4)

Amanda:

I hate to add to your load but, I would appreciate you asking. Alternatively, if you tell me who I should call I can speak to them. For COI I have been working with Duane Stone.

Best,

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
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Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu
<image001.png>

From: "Cohn, Amanda (CDC/OID/NCIRD)" <anc0@cdc.gov>
Date: Tuesday, July 17, 2018 at 9:37 AM
To: "Romero, Jose" <RomeroJose@uams.edu>
Subject: RE: Save The Date: August 25th (b)(4) (b)(4)

Hi Jose,

This is a good question, I'm not sure. Do you want me to review this with others at CDC and get back to you?

Amanda

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Monday, July 16, 2018 11:09 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: FW: Save The Date: August 25th (b)(4) (b)(4)

Amanda:

Am I allowed to do this?

Jose

From: Brandon Wan [mailto (b)(6)
Sent: Monday, July 16, 2018 9:30 AM
To: Romero, Jose
Cc (b)(6)
Subject: Save The Date: August 25th - (b)(4)
(b)(4)

Dear Dr. Romero:

On behalf of (b)(4) we would like to cordially invite you to the (b)(4)
(b)(4)
(b)(4) You will receive a formal invitation in the coming weeks from (b)(4) where you will be able to register to attend. In the meanwhile, we would appreciate it if you could reply this e-mail to let us know of your interest and availability. If you are available, please add this meeting to your calendar and we will follow up with an invitation and then issue you a consultant agreement before booking your travel. Thank you.

(b)(4); (b)(6)

(b)(4); (b)(6)

From: Lee, Grace
Sent: Tue, 2 Feb 2021 17:52:38 +0000
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Jose Romero
Subject: Re: Vaccine Education - press opportunities

Thank you, Jessica. Appreciate the check on this.

Best
Grace

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Date: Tuesday, February 2, 2021 at 7:16 AM
To: Lee, Grace <GMLee@stanfordchildrens.org>, Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>, Jose Romero <Jose.Romero@arkansas.gov>
Subject: RE: Vaccine Education - press opportunities

Hello Grace,

Thanks for reaching out about this! From our perspective it would be totally fine for you to participate in this and would not represent a conflict of interest.

Thanks,
Jessica

From: Lee, Grace <GMLee@stanfordchildrens.org>
Sent: Monday, February 1, 2021 7:52 PM
To: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Jose Romero <Jose.Romero@arkansas.gov>
Subject: FW: Vaccine Education - press opportunities

Dear Jessica, Amanda and Jose

Got asked to do this. Though just checked their leadership and one Board member is from J&J. I would love to help them, but I'm assuming this could be construed as a conflict of interest?

Thanks much
Grace

From: (b)(6)
Date: Monday, February 1, 2021 at 3:42 PM
To: Lee, Grace <GMLee@stanfordchildrens.org>
Cc: (b)(6)
Subject: Vaccine Education - press opportunities

Hi Dr. Lee,
I work on the Ad Council and COVID Collaborative's COVID-19 Vaccine Education Initiative, and Hemi Tewarson suggested you would be a great speaker to be connected to.

(b)(4)

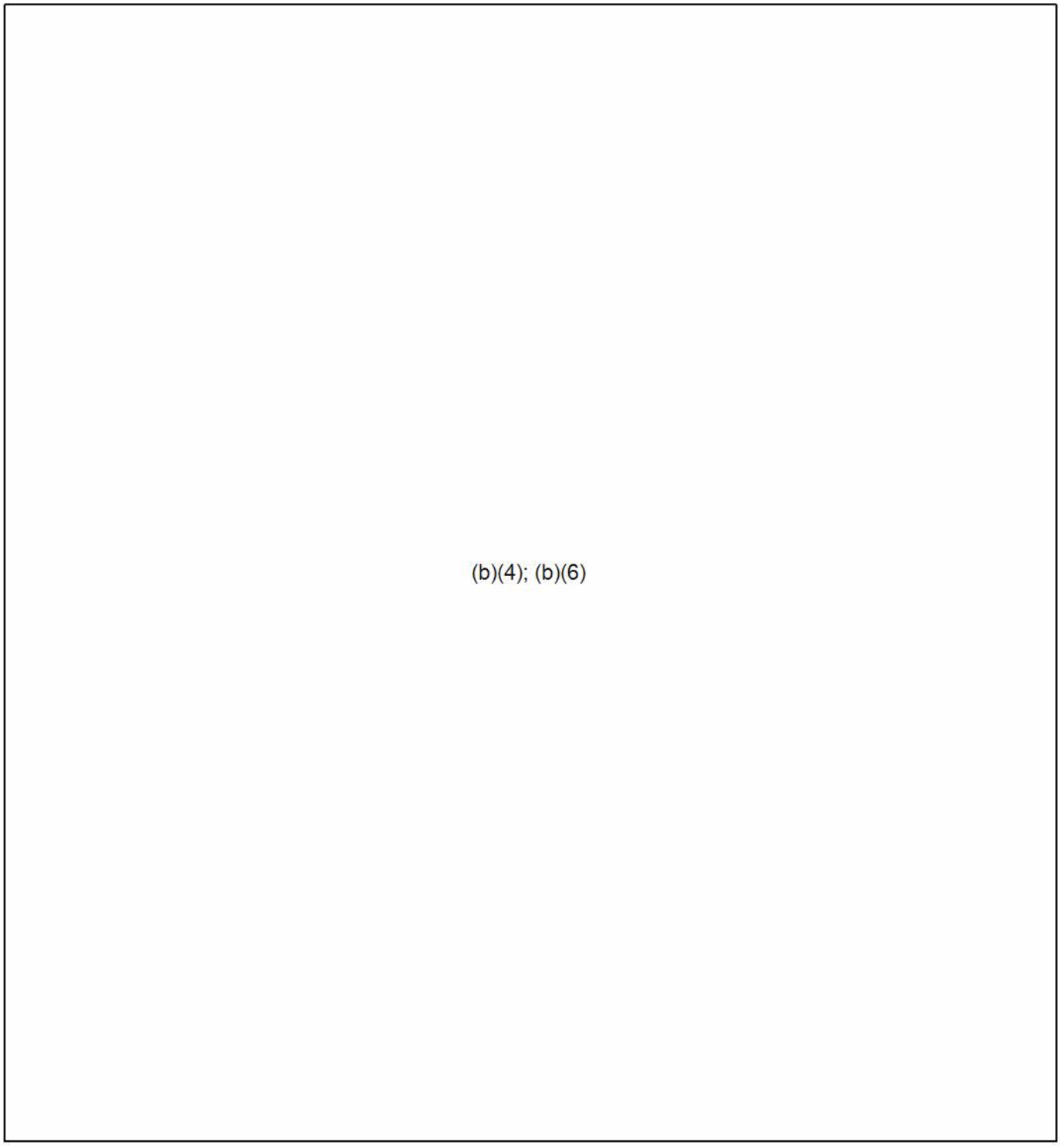
We'd love to have you participate, but of course, if your schedule doesn't allow for interviews at this time, just let me know.

If this is of interest, we'd appreciate you confirming the following details, this week if possible:

- Name: Dr. Grace M. Lee, MD
- Title, Organization: Associate Chief Medical Officer for Practice Innovation and Professor
- Location: Stanford, CA
- Key topics you can speak to (as related to COVID-19 vaccination):
- Spokesperson bio and headshot: *https://www.stanfordchildrens.org/en/doctor/grace-m-lee* *Please also send the headshot as an attachment if possible*
- Best contacts for the Ad Council/our PR agencies to coordinate with as opportunities arise:
- Language(s) you are comfortable giving interviews in:

(b)(4)

(b)(4) *If so, we'll follow up with more details about that opportunity.*


(b)(4); (b)(6)

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Mon, 27 Nov 2017 21:53:22 +0000
To: Bernstein, Henry; freyse@slu.edu
Cc: Bennett, Nancy M.; RomeroJose@uams.edu; MacNeil, Jessica R. (CDC/OID/NCIRD); Thomas, Stephanie B. (CDC/OID/NCIRD) (hkp4@cdc.gov)
Subject: Welcome new ACIP members!

Dear Hank and Sharon,

Your final packages have been approved for your appointments to ACIP! We appreciate your being patient with the process for the past year, and of course now that everything has been approved we are going to be sending you mounds of paperwork for you to complete so we can get you on board and ready before the February meeting.

Stephanie Thomas is the ACIP Committee Management Specialist, and she will be sending you paperwork via FedEx. If you could please send her your home address, or a place where you know you will get the package, that would be great.

Jessica MacNeil is the ACIP Deputy Executive Secretary, and as soon as we start your paperwork processing we will set up an orientation for you. You may also be receiving emails from Duane Stone related to completing your conflict of interest paperwork.

We will give you each a call in the next couple of days to give you an official welcome, but I did not want to finish the day without letting you know. We look forward to having you!

Amanda

Amanda Cohn, MD
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