OVERSIGHT COMMITTEE GUIDANCE ON REVIEW OF COI

GENERAL POLICIES:

1. In creating evidence-based guidelines and consensus statements that clinicians and the public will trust, PHEX must limit the potential for bias through careful vetting, evaluation, and management of the financial relationships and intellectual activities of each potential participant.
2. All potential panelists will be required to submit a complete disclosure prior to the initiation of guideline/consensus statement development. Panelists' disclosures and contributions to the field will be reviewed both as individuals and in aggregate to achieve a balanced panel.
3. The scope of disclosure will include a 4-year period and will capture the personal potential COIs. For financial disclosures, peso amounts must be provided for both monetary and in-kind remuneration. The OC will take into account a person's ability to divest of activities that may be viewed as disqualifying conflicts and may include divestment as a condition for participation for specific COIs.

   All panelists will agree to divest from all disqualifying relationships at time of nomination and to adhere strictly to any COI management terms and will not assume any new relationships until a minimum of 1-year post-publication of the document (or another time period to be designated by the OC) without the expressed written preapproval of the CSC Chair. Each panel meeting will begin with a verbal reminder of this policy.

4. All potential COIs, even those that appear to be indirectly related to the topic, and management terms will be publicly disclosed through publication in the final article, and the COI management process will be addressed in the methodology section of the final guideline/consensus statement to ensure readers have complete and transparent detail.

General Definitions:

- Commercial interest/entity is any for-profit entity producing, marketing, re- selling, or distributing health-care goods to be consumed by or used on patients (e.g., pharmaceutical or device companies).
- Conflict of Interest (COI) refers to any relationship or other set of known circumstances that has the potential to bias, or that might be reasonably perceived by others to bias, an individual's judgment, conduct, or other work.
- Financial COIs include any relationship for which one receives remuneration or in- kind benefits that could be perceived to affect one's judgment in the evaluation of specific recommendations. These include holdings in individual investments (e.g. holdings in

stocks, stock options, warrants, bonds, or any form of direct investment of pharmaceutical or device companies), and patents associated with licensing, and/or financial or in-kind benefit; and these include such holdings held by the guideline participant.

- Intellectual COIs include any activities that create the potential for attachment to a specific predetermined point of view that could be perceived to affect one's judgment in the evaluation of specific recommendations or suggestions.
- Related content areas are those that are aligned with the clinical questions and/or PICO elements (patient-intervention-comparator-outcomes) to be addressed within the guideline.

PROCESS

A. Guideline Approval, COI Collection, Panel Formation

1. Staff will initially send the CV & disclosure of COI of the proposed Chair and/or Vice-Chair/Co-Chair and Technical Coordinator to the Central SC
2. Once Central SC formally approves the guideline topic, TF staff will invite proposed panelists to submit their CVs and disclosure forms within a 2-week period. Complete forms will be forwarded to the OC in aggregate with the draft clinical questions (and their PICO elements) to be addressed by the guideline, enabling the OC to review conflicts, relevance, hold discussions, and make determinations on individual panelists. In the rare circumstance that PICOs are not available, panelists who are approved with management will be re-reviewed once the PICO questions are defined.
3. A letter of all decisions made by the OC—or requests for additional information—on a panel will be sent to the TF SC.
4. Each candidate receiving a management plan or disapproval will receive a call or an email from the Chair or Vice-Chair of the TF prior to the formal decision letter being sent. Discussion will include divestment from COI, management terms, the process to vet any newly proposed relationships or activities that might occur while on the guideline, and a review of the appeal process.
5. TF will issue final decision letters on behalf of the OC, copying the Central SC Chair, and OC.

B. Appeals

Decisions related to Chair, Vice-Chair, and panelist-level participation and/or management terms made by the OC may be appealed through written request. The submitter should include any additional information and the potential justification for determination of a different decision. The appeal will be considered by a joint group of five individuals from the Central SC and OC, led by the Chair of Central SC, and will serve as the final arbiter. The appeals body includes the (1) Central SC Chair, (2) Central SC Vice-Chair, (3) OC Chair, and (4) OC Vice-Chair (5) SC/OC member.

C. Review and Categorization of COIs

In reviewing submitted disclosure forms, determining the relevance of each disclosure is paramount. Conflicts that relate directly to the disease, diagnostic techniques, interventions, or management being evaluated are said to be *primary*; those that do not relate directly are characterized as *secondary*. This distinction will often form the basis for differentiating between manageable and disqualifying conflicts. The scope of an individual's activities is also considered in aggregate. While an amount on a single activity may not be particularly high, a large number of relationships (e.g., advisory board activities) that total a substantial amount may lessen public trust in the document that results. In reviewing grant-related relationships, it is important to take into account who receives the funding (institution vs individual) and whether direct salary support is provided.
First degree affinity & consanguinity – parents, legal spouse & children, domestic Partner (primary)
Second degree – siblings, grandparents (secondary)

Disclosure of COIs over the last 4 years is required; however, emphasis will be placed on the last year of COIs when vetting candidates for guideline panel positions. COI disclosures must clearly explain the relationship, related disease topics involved in the relationship, and dates of payment for stated services.

In evaluating total panelist participation, constructing a panel wherein only a minority of members have conflicts of interest requiring management is ideal. All conflicts of interest, including those deemed acceptable and those deemed manageable, will be reported throughout the guideline development process and disclosed in final publication.

Acceptable Relationships and Activities
In general, acceptable relationships and activities include those that are:

1. Intellectual in nature and lacking direct and indirect financial benefit; or
2. Unrelated to the content area and focus of the PICO question or recommendation, with a company that has no products in that specific topic area.

Where intellectual conflicts exist, relationships should be disclosed to the group of panelists throughout the development process and included in the final publication. The remaining types of activities listed require disclosure but no proactive management.

Manageable Relationships and Activities

For certain types of relationships, the OC, through the Chair (and Vice-Chair/Co-Chair), will develop and oversee individualized, formal, and transparent management plans that will delineate any limitations on participation defined as a result of the relationships.

For those individuals who are approved with management, the specific terms of management will be set forth by the OC and will relate to specific clinical questions/PICOs and limit participation in the following way:

Manageable A – usually if there are intellectual conflicts of interest only. They can vote but they need to declare their intellectual conflicts (e.g. affiliation with institutions, positions in an organization, authorship in paper or CPG)

Manageable B – For some intellectual and financial conflicts of interest, panelists cannot vote but they can share their expertise to the group. Examples include panelists from gov't agencies directly involved in the implementation of the program and panelists from the agency funding the guidelines. The specific terms of management shall be set forth by the Oversight Committee (OC) and shall relate to specific clinical questions/PICOs.

• May participate in discussions, but may not vote, or grade recommendations relevant to specific conflicts (note content/clinical question).

The scope or nature of some relationships negates management and will sometimes outweigh the content expertise an individual may bring by serving as a full panelist, resulting in
disqualification.

*Note: The above are not based only on the possible conflicts of interest but also on any perception thereof.

Disqualifying Relationships and Activities

The scope or nature of some relationships negates management and will sometimes outweigh the content expertise an individual may bring by serving as a full panelist, resulting in disqualification.

In some cases, a potential panelist may be given the opportunity to divest of a relationship(s) instead of being disqualified. Participant must divest prior to initiating work on the guideline and for a minimum duration of 1 year post-publication.

The ability to apply management terms also assumes that there is a portion of the guideline for which the individual would be considered nonconflicted and on which they could fully participate. In instances in which a person's relationships are manageable but relate to the entire guideline and all PICOs, the result would also be disqualification.

Categorization of Relationships and Activities by Role

***Guidance for COI (adapted from DOH & ACCP)**

Type of Relationship/Activity	Chair, Co-chair, SC members	Methodologist/ Technical Coordinator	Consensus Panelist
Research & Scholarly Activities			
1. Authorship of original material in support of a commercial entity			
1.1 Author/co-author of a published (original) paper related to the CPG topic	Disqualifying	Disqualifying	Manageable B
1.2 Senior editorial role or assignment related to the CPG topic	Disqualifying	Disqualifying	Manageable B
2. Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with a financial interest related to the CPG topic?			
2.1 Research support, including grants, collaborations, sponsorships and other funding with a direct financial interest related to the subject of the CPG	Disqualifying	Disqualifying	Manageable B
2.2 Support (including honorarium of over Php 50,000 for a span of six months) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with a direct financial interest related to the subject of the CPG	Disqualifying	Disqualifying	Manageable B
2.3 Research support, including grants, collaborations, sponsorships and other funding with an indirect financial interest related to the subject of the CPG	Disqualifying	Manageable B	Manageable A
2.4 Support (including honoraria)for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an indirect financial interest related to the subject of the CPG	Disqualifying	Manageable B	Manageable A
Advisory / Consultancy Engagements			

3. Non-financial interests: Are you engaged in any professional or other activities which outside parties would consider might represent or give rise to a conflict of interest, with regard to your CPG work	*Declarations in this section do not necessarily represent conflict of interest. The OC needs to examine the declarations closely to determine any adverse effect on the credibility of the guidelines. Appropriate management /ratings will depend on discussions		
3.1 Official function in a government agency or international organization	Disqualifying	Disqualifying	Manageable B
3.2 Advisory committee associated with a public or private sector organization	TBD	TBD	TBD
3.3 Board member of a public or private sector , non-profit organization or an advocacy group	Disqualifying	Manageable B	Manageable A
3.4 Consulting (as technical or other advisor on a related topic	TBD	TBD	TBD
Public Statements			
4. Issuing statements on an unrelated topic on behalf of a commercial entity			
4.1 Have given expert testimony (with regard to any regulatory, legislative or judicial process) related to the subject of the CPG, on behalf of a commercial entity or other organization	Disqualifying	Disqualifying	Manageable B
4.2 Held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the CPG (on behalf of a commercial entity)	Disqualifying	Disqualifying	Manageable B
Intellectual property & Investments			
5. Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the CPG?			
5.1 Patents, trademarks, or copyrights (including pending applications) related to topic	Disqualifying	Disqualifying	Disqualifying
5.2 Proprietary know-how in a substance, technology or process related to topic	Disqualifying	Disqualifying	Disqualifying

6. Investments (e.g. stock holdings, stock options, warrants, shares, bonds, or any other form of direct investment (not as part of mutual fund) in pharmaceutical companies or any other commercial entities (e.g. device manufactures) that manufacture or sell products related to management of an individual with disorders addressed *that will give significant benefit (no more than 0.1% of the total stocks of the hospital)			
6.1.with stocks in hospitals (specific to PHEX)	Manageable A Disqualifying if >0.1%	Manageable A Disqualifying if >0.1%	Manageable A, Manageable B if >0.1%
6.2 With Stocks, bonds, stock options, other securities (e.g., short sales) in topic area - pharma or device company	Disqualifying	Disqualifying	Disqualifying
6.3 Commercial business interests (proprietorships partnerships, joint ventures, board memberships, controlling interest in a company - pharma or device company	Disqualifying	Disqualifying	Disqualifying
Employment			
7. Full-time/part-time employment with a commercial entity with financial interest			
7.1 Employment related to topic	Disqualifying	Disqualifying	Disqualifying

Appendix A:
Conflict of Interest Terminology

Commercial Advisory Boards, Committees, or Engagements: Serving on a committee or board organized by a commercial entity on a topic related to a company project, product or promotion.

Authorship: Listed among the authors of a manuscript or other publication that is intended for distribution (first, middle or last author). Being listed in the acknowledgement section does not count as authorship.

Commercial Educational Activity: Educational forum organized/supported by a commercial entity. Examples include satellite symposia, pharmaceutical or device manufacturer organized educational events, local sponsored lectures, or any talk/presentation using any industry branded, generated, or facilitated slides.

Commercial Entity:
A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The OC does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by a commercial entity.

Conflict of Interest: Any relationship or other known set of circumstances that has the potential to bias or might reasonably be perceived by others to bias, an individual's judgement, conduct or other actions.

- **Financial COI:** Any relationship for which one receives remuneration or in-kind benefits that could be perceived to influence one's judgement in the evaluation of specific recommendations. These include relationships by the participant, their spouse, domestic or life partner, dependent children and minors living in the same household.
- **Intellectual COI:** Any activity that creates the potential for attachment to a specific predetermined point of view that could be perceived to affect one's judgement in the evaluation of specific recommendations or suggestions.
- **Related content area:** Those that are aligned with the clinical questions and/or PICO elements to be addressed within the guideline or recommendation.

Consultancy: Time-limited business relationship with a commercial entity, where the consultant provides professional input regarding a project, product, or medical topic. To comprise a COI, the consultant must receive some remuneration for their participation which includes in-kind payments such as travel expenses.

Expert Testimony: Testimony made by a qualified person about a scientific, technical, clinical, or professional issue. A key distinction is whether one provides testimony in support of (or opposition to) a pharmaceutical or device company (which must be managed or is prohibited, depending on one's leadership level/guideline position with or for a patient which is acceptable.

Employment: Refers to a contractual arrangement where the employee performs a service which is paid for by the employer.

Faculty: Presenter or moderator at an educational or promotional event

Guideline Panelist: Any person who contributes to the work of developing the guideline (e.g. defining the scope, forming the clinical questions, searching and evaluating the literature, developing recommendations or suggestions, voting, and drafting the manuscript) and includes an expectation of authorship, provided they meet the criteria defined by the International Committee of Medical Journal Editors.

Investigator: Investigators on a project usually receive remuneration for their role on the program/project. This typically includes Principal Investigators and Co-Investigators, but not consultants (paid or unpaid). Forms of remuneration include monetary compensation, equipment, travel, or supplies.

Speakers Bureaus: Being identified as a company sponsored speaker for an educational event where slides or content are at least in part supplied by the company

- If Pharma gives money to an institution or not-for-profit organization (assuming that organization is not financially linked to a pharmaceutical or device manufacturer) to host an event, it is required that the talk title, the talk content, speakers, and all funds be negotiated and managed by the institution/organization

Patent Holder or Applicant: Being listed as the sole or one of several inventors of some disclosed intellectual property submitted for patent consideration.

Promotional Activities: Those activities that support, market, or increase sales or consumption of a specific drug, device, technology, or technique, or that are intended to enhance the image, well-being, stature or popularity of a commercial entity pertinent to medicine, independent of remuneration.