



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 22 2020

ADMINISTRATIVE ORDER

No. 2020 - 0061

SUBJECT: Guidelines on the Public Health Ethics Review and Creation of the DOH Public Health Ethics Committee

I. RATIONALE

The Department of Health (DOH), under Executive Order No. 102 s, 1999 entitled "Redirecting the functions and operations of the Department of Health", is mandated to develop public health programs, to undertake disease surveillance and maintain health information systems, and to perform research designed to support and evaluate policies. These activities fundamentally deal with people and are all subject to ethical inquiry.

The primary value of any public health activity must be the potential improvements to the health of individuals and communities. This value may be compromised when healthcare professionals' professional and personal interests are prioritized over the public health interest.

The implementation of Universal Health Care shall be strengthened by commitment of all stakeholders to abide by ethical principles in public health practice. Sections 35.6 and 35.7 of the Universal Healthcare Act (R.A. 11223) Implementing Rules and Regulations (IRR) stipulates that a public health ethics review committee shall be constituted as an advisory body to the Secretary of Health to assess the ethical soundness of public health practice.

This Order is hereby being issued to provide the framework for the creation of the Public Health Ethics Committee (PHEC) and the processes for the ethical review of Conflict of Interest declarations and financial relationships with manufacturers of drugs, medical devices, and biological and medical supplies.

II. OBJECTIVES

General Objective:

This Order aims to operationalize public health ethics review to ensure that the risks from conflict of interest from individuals, groups, organizations and institutions and financial relationships with healthcare professionals and health care providers by all manufacturers, traders and distributor-importers of drugs, medical devices, biological and medical supplies registered by the FDA will not impact on the decision-making process relative to policy-determining activities of the implementing agencies and advisory bodies/committees of the UHC Law.

Specific Objectives:

1. To provide the general framework and guidelines on the ethics review process for COIs and financial relationships with manufacturers of drugs, medical devices, and biological and medical supplies.

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CORAZON S. DELA CRUZ, Secretary
KMTS - RECORDS SECTION
Department of Health
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2. To define the organization and composition of the Public Health Ethics Committee (PHEC).
3. To identify the roles and responsibilities of key actors and stakeholders.

III. SCOPE OF APPLICATION

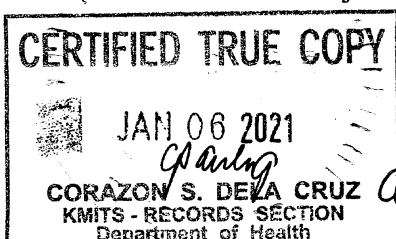
This Order shall apply to all decision makers, policymakers, employees, personnels under contract of service and consultants involved in the design, institutionalization, financing, procurement, implementation and evaluation of public health policies, plans and programs in the Department of Health and its attached agencies, and all other concerned government agencies providing/performing health-related activities.

IV. DEFINITION OF TERMS

1. **Conflict of Interest** – refers to acts or omissions constituting a conflict of interest under existing laws and civil service rules, including international treaties where Philippines is a signatory. It is a situation created when persons or entities in the public and/or private sectors involved in conducting research, making recommendations and decisions have substantial interest – personal, financial or any other interest – that may influence their policy-determining activities at all levels.

For the purpose of this Order, this shall mean either:

- a. Financial Interest, such as, but not limited to, employment, consultancy, and shares in a business that is being regulated by the DOH of persons covered under this Order or any of their relatives as defined herein; OR
 - b. Affiliation/relationship/non-financial interest in a business or organization that can reasonably affect or perceived to impair a person's ability to be impartial and act in the best interests of the government.
2. **COI Management Plan** - refers to a document describing the methods for mitigating or eliminating identified actual or potential COI.
 3. **Declaration of Conflict of Interest Form** - the standard form that will be used for persons covered under this Order to disclose any and all conflicts of interest.
 4. **Financial Interest** - refers to any monetary interests gained for the past 5 years; i.e. salary or other payments for services or equity interests such as stocks, stock options, intellectual property rights, among others.
 5. **Full Participation** - the extent of participation where a member will be allowed to actively take part in all activities and decision-making processes.
 6. **Non-financial Interest** - refers to any non-monetary interest, e.g., career or personal advancement that may be perceived as unduly influencing one's judgment
 7. **Originating Office** – refers to all agencies, bodies, or committees tasked to implement any of the provisions in the UHC Act.
 8. **Partial Participation** - the extent of participation where a member will be allowed to actively take part in only certain parts of activities and decision-making process subject to the approval of the members who have full participation.



9. **Public Health Practice** - refers to the conduct of governmental activities that protect the public's health, including performing oversight functions for these activities (Adapted from: *Otto, J. L., Holodniy, M., & DeFraitess, R. F., 2014*).
10. **Public Health Ethics** - refers to the application of relevant ethical principles and values to guide public health decision making. (CDC, 2015).
11. **Total Exclusion** - a situation where the member will not be allowed in any step of the deliberation and decision-making processes.

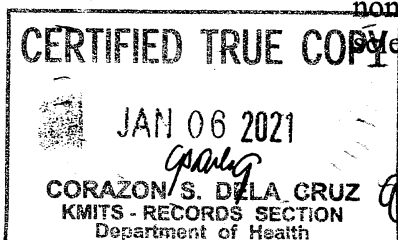
V. GENERAL GUIDELINES

- A. Implementing agencies and advisory bodies/committees covered under this Order shall be guided by the following principles of public health ethics in any health or health-related decision-making:
 1. **Beneficence** - Public health involves a moral obligation to promote and protect the welfare of individuals and communities.
 2. **Respect to rights of individuals and of the community** - Public health institutions and their employees should engage in collaboration and affiliation in ways that build the public's trust and the institution's effectiveness.
 3. **Professionalism** - Public health institutions shall ensure professional practice from their employees at all times.
- B. Conflict of interest (COI) of individuals, groups, organizations, and institutions involved in policy development and decision-making must be recognized, declared, and acted on to ensure that policies and decisions are not influenced by any financial or non-financial interests.
- C. The DOH shall constitute a Public Health Ethics Committee (PHEC) supported by a Secretariat to review declared actual and potential conflicts of interest and financial relationships with manufacturers of drugs, medical devices, and biological and medical supplies.
- D. Implementing agencies and advisory bodies/committees covered under this Order with identified COI, whether actual or potential, shall submit a corresponding COI management plan together with the declaration of COI form.
- E. The declaration and management of conflict of interest shall be guided by existing policies, namely: Department Order 2017-0332 or the *Guidelines on the Disclosure and Management of Conflict of Interest (COI) in relation to the Use of Pharmaceutical Products and Medical Devices*; and Department Order 2019-0163 or the *Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals*. Any other issuance on COI hereafter shall also be applicable.

VI. SPECIFIC GUIDELINES

A. Public Health Ethics Committee and Secretariat

1. **Committee Composition.** The PHEC shall consist of five (5) permanent members namely: a public health expert who will serve as the chair, an ethics advisor, a lawyer who is not affiliated with the DOH, a representative from a non-governmental association (NGA) or patient groups, and a lay person (non-scientific person).



2. Minimum Qualifications of PHEC members

- a. Recognized expert in his/her field of practice;
- b. Knowledgeable about integrity management or corruption risk management initiatives and public health ethics;
- c. Knowledgeable about analysis of ethical issues particularly conflict of interest;
- d. Familiar with the process of identifying, analyzing and resolving issues involving financial and non-financial COI

3. **Resource Persons.** The PHEC may call upon resource persons to provide specific subject matter expertise during the review process.

4. **Nomination Process.** Nomination of PHEC members shall be solicited from the stakeholders of public health.

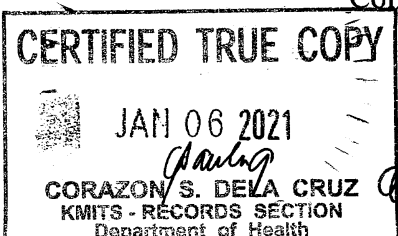
5. **Selection.** The PHEC members shall be appointed by the Secretary of Health for a term of three (3) years. In order to ensure continuity of functions, at least half of the PHEC shall be retained/re-appointed for at least one (1) year before a new set shall be appointed. Members may also be re-appointed to a full term of three (3) years.

6. **Scope of Work.** The PHEC shall function as an advisory body that:

- a. Determine the presence of actual or potential COI and financial relationship among individuals involved in the development, institutionalization, financing, implementation (including procurement), monitoring and evaluation of the public health policies, plans and programs
- b. Check, keep track, address and manage all Declaration Reports and determine any actual and potential conflict of interest that may affect or impact DOH and other government health-related project, program, activity, commitment or event, among others.
- c. Provide recommendation and/or actions to manage or eliminate actual or potential COI.
- d. Conduct inquiries as may be necessary to address conflict of interest issues.
- e. Provide recommendatory decisions/actions to the Secretary of Health based on the review of declaration of COI form and other supporting documents (as applicable).

7. **Duties and Responsibilities.** The PHEC permanent members and resource persons shall abide by the details of engagement and the public health ethics review process.

8. **Per Diem.** The PHEC chair and members shall receive per diem for every meeting facilitated and attended, following the provisions of the Department of Budget and Management (DBM) National Budget Circular No. 2003-6 "Guidelines Relative to the Grant of Per Diems to members of Collegial Bodies and Members of the Board of Regents/ Trustees of State Universities and Colleges", or its amendments.

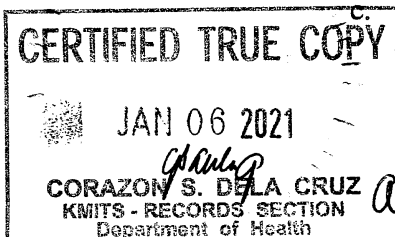


9. **Secretariat.** The Secretariat shall consist of technical staff and administrative staff from the DOH HPDPB and the Food and Drug Administration, who shall provide support to the day-to-day operations of the PHEC.
10. **Disclosure of Conflicts of Interest.** The PHEC Chair, permanent members, resource persons and secretariat shall comply with the latest policies and guidelines of the DOH for declaring and managing conflict of interest.

B. Public Health Ethics Review Process

1. The originating office shall ensure that all individuals or institutions involved in the design, implementation and evaluation of public health policies, plans and programs shall declare actual or potential COI.
 - a. The originating office shall submit a duly accomplished Conflict of Interest Declaration Form (*Annex A*) of all individuals and institutions involved in the policy development and decision-making process. It shall cover financial and non-financial interests up to the fourth level of consanguinity and affinity.
 - b. The originating office shall submit a corresponding COI management plan for all identified actual or potential conflicts of interest.
2. The PHEC Secretariat shall ensure completeness of documents submitted by originating office.
3. The PHEC secretariat shall conduct an initial review of the submitted documents to determine the magnitude, timeframe and duration of the interest. The PHEC Secretariat shall determine whether the declared COI and financial relationship qualify under any of the following: not significant or generally permissible; and, significant enough to potentially affect policy development and decision-making. In case of the latter, the PHEC Secretariat shall recommend to the chair an appropriate review procedure.
4. The PHEC secretariat shall facilitate PHEC review procedures based on the identified level of COI, as approved by the PHEC Chair.
 - a. Significant COI, whether actual or perceived shall undergo full committee review.
 - b. Not significant or generally permissible COI shall undergo expedited review.
3. The PHEC shall recommend an appropriate course of action based on their review of the declaration of COI form, corresponding COI management plan, and other supporting documents (as applicable).
 - a. **Full Participation** - if the declared COI is deemed to impose less than minimal to no impact on the policy development and decision-making process.
 - b. **Partial Participation** - if the declared COI is deemed to impose significant impact on the policy development and decision-making process and can be mitigated or eliminated

Total Exclusion if the declared COI is deemed to impact significantly on the policy development and decision-making process and cannot be mitigated or eliminated



5. The PHEC shall present to the Secretary of Health, as part of the regular Execom Agenda, their report, which includes statement of the facts, discussion, and recommendations.

C. Financial and Non-financial Conflict of Interest (COI)

Actual or potential conflict of interest that shall be disclosed include, but not limited to, the following:

1. Financial interest relevant to the policy-determining activity in which they are participating in as well as any interest that can be affected by the outcome of their actions irrespective of amount: Significant financial interest exists if the value of any outstanding equity (e.g., stock, securities, or other ownership/business interest) or remuneration received in twelve (12) months preceding the disclosure, exceeds aggregate value of Two Hundred Fifty Thousand Pesos (Php 250,000.00).
 - a. Employment and consulting within the 12 months, such as being employed by a commercial sponsor of clinical research and/or engagement to paid speaking engagements, and hold position on marketing and medical advisory boards;
 - b. Employment and consulting of parents, household members, children, and relatives until 4th degree of consanguinity or affinity;
 - c. Research support for the expert's own research and that of his or her unit, including supplies and equipment;
 - d. Financial interest in the form of bonuses or increase in payments after fulfillment of specified number of participants enrolled in clinical trials;
 - e. Financial interest such as ownership of stock and equity, other securities, business interests, receipt of honoraria;
 - f. Financial interest from intellectual property (e.g., patents, publications, licenses and royalty rights)
 - g. Travel and attendance to trainings and continuing education (e.g., CME, CPD) or other instructional sponsorships;
 - h. Financial agreements linked to the outcome of the clinical trial;
 - i. Any proprietary interest in the investigational product.
2. Non-financial interest that may be perceived as unduly influencing one's judgement:
 - a. Personal and professional relationship that includes, but is not limited to, the following:
 - i. Family relationships up to the fourth level of consanguinity and affinity, as well as anyone sharing the employee's household
 - ii. Friends or adversaries
 - iii. Volunteer commitments;
 - b. Conflict of commitment with other institutions and/or activities and programs;

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- c. Involvement in institutional decisions or consulting positions concerning the purchase or approval of medications or equipment, or the negotiation of other contractual relationships over the investigational product or result of the study;
 - d. Any proprietary interest in the investigational product.
3. Other forms of compensation/ incentives:
- a. Recruitment incentives i.e., referral system, finder's fee;
 - b. Financial or non-financial augmentation of salary;
 - c. Non-research travel and other gifts.

D. Management of Conflict of Interest (COI)

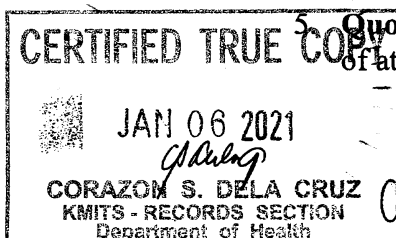
The following are examples of specific actions that may be taken to manage COI:

- 1. Public COI declaration e.g. when representing the institution/hospital in meetings, or when presenting or publishing;
- 2. Disclosure of financial conflicts of interest directly to individuals or communities that will be affected by the public health policy or program;
- 3. Change of personnel or personnel responsibilities;
- 4. Reduction or elimination of the financial interest (e.g., sale of an equity);
- 5. Modification of public health policy or program implementation plans;
- 6. Definition of boundaries and prohibitions;
- 7. Disqualification of the declarant from participation in the design, implementation and evaluation of public health policies and programs; and
- 8. Severance of relationships that create financial or non-financial conflicts.

E. Standard Operating Procedures (SOP)

The SOP for the public health ethics review shall be made available through the issuance of a Department Circular. This shall serve as the reference document and shall be periodically revised and updated. The following are the key provisions in the SOP:

- 1. **Requirements for Submission.** The PHEC shall require conflict of interest declaration and COI management plan to be submitted by implementing agencies and advisory bodies/committees covered under this Order for review by the PHEC.
- 2. **Frequency.** The PHEC shall convene at least once a month, or more frequently depending on the volume of submissions.
- 3. **Schedule.** The PHEC meeting is regularly scheduled on the second Thursday of the month.
- 4. **Timeline of reviews.** Review recommendations shall be available within 14-30 calendar days after submission of complete requirements.
- 5. **Quorum.** The meeting shall proceed if the quorum requirement of attendance of at least 50% + 1 of the permanent committee members.



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6. **Recommendations.** Recommendations are arrived at through consensus of permanent committee members present.

VII. ROLES AND RESPONSIBILITIES

A. Health Policy Development and Planning Bureau

1. Provide the overall technical and administrative support to PHEC;
2. Ensure completeness of documents submitted for an efficient review;
3. Initiate training and other capacity building activities to promote ethical practice in public health;
4. Ensure transparency of reviews coursed through the PHEC; and
5. Allocate funds and provide support to operationalize the public health ethics review process.

B. DOH units including Central Office bureaus, Centers for Health Development, hospitals, and line/attached agencies and partners from the private and public health sectors

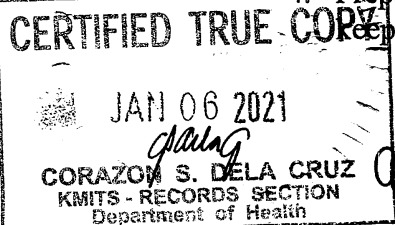
1. Comply with the standards on receipt, assessment, and management of conflict of interest.
2. Develop a COI management plan corresponding to the identified actual or potential COI.
3. Submit the declaration of COI form and corresponding COI management plan to the PHEC for review.
4. Ensure strict compliance to the PHEC review process mechanism through recognition of its decisions and recommendations.

C. Public Health Ethics Committee Members

1. Review summary documents on reported COIs and financial transactions;
2. Provide recommendation and/or actions to address actual or potential COI through casting of votes for recommendation determination;
3. Provide recommendatory decisions/actions to the Secretary of Health based on their review;
4. Declare any conflicts of interest pertinent to their role in the review or their relationship with individuals or institutions declaring COI.

D. PHEC Secretariat

1. Receive all COI and other related documents emanating from concerned DOH units;
2. Conduct initial screening of declaration of COI form and other related documents;
3. Shortlist nominations for PHEC members based on a standard criteria;
4. Prepare administrative support and logistics during meetings e.g., record keeping and documentation of proceedings.



VIII. REPEALING CLAUSE

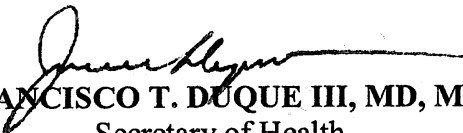
Other related issuances not consistent with the provisions of this Order are hereby revised, modified, or rescinded accordingly. Nothing in this Order shall be construed as a limitation or modification of existing laws, rules and regulations.

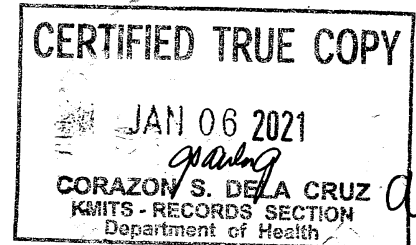
IX. SEPARABILITY CLAUSE

Should any provision of this Order or any part thereof be declared invalid, the other provisions, insofar as they are separable from the invalid ones, shall remain in full.

X. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in the Official Gazette or a newspaper of general circulation and submission to the Office of the National Administrative Registry (ONAR) at the UP Law Center.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health



ANNEX A

DECLARATION OF CONFLICT OF INTEREST

1. CURRENT FINANCIAL INTERESTS

To the best of your knowledge, do 1) you or any of your relative within the fourth (4th) civil degree, by affinity or consanguinity, 2) organization in which you serve as an officer, director, trustee, general partner, or employee and/or 3) entity with whom you are negotiating or have any arrangement concerning prospective employment have any current involvement or financial link with any policy determining activity of the office/agency/advisory body/committee:

a. **INVESTMENTS** (e.g. stocks, bonds, retirement plans, trust, partnerships, sector funds, etc.)

☐ **NONE** (If "none", skip to Item b.)

ESTABLISHMENT	TYPE OF INVESTMENT	OWNER (self, spouse, etc.)	NUMBER OF SHARES	CURRENT VALUE	CHECK PERCENTAGE NET WORTH		
					LESS THAN 5%	5-15%	MORE THAN 15%

b. **EMPLOYMENT** (Full or Part Time) (Current or Under Negotiation)

☐ **NONE** (If "none", skip to Item c.)

ESTABLISHMENT	RELATIONSHIP	POSITION IN FIRM	DATE EMPLOYMENT OR NEGOTIATIONS BEGAN

c. **CONSULTANT/ADVISOR** (Current or Under Negotiation)

☐ **NONE** (If "none", skip to Item d.)

ESTABLISHMENT	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES

d. **CONTRACTS/GRANTS** (Current or Under Negotiation)

☐ **NONE** (If "none", skip to Item e.)

TYPE OF AGREEMENT (contract, grant)	PRODUCT UNDER STUDY AND INDICATIONS	AMOUNT OF REMUNERATION TO		TIME PERIOD	SPONSOR*	YOUR ROLE**	AWARDEE	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
		INSTITU- TION	YOU					
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO

* Government, Establishment, Institution, Individual

** Site Investigator, Principal Investigator, Co-Investigator, Employee, Partner, No Involvement, or Other

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES

1. CURRENT FINANCIAL INTERESTS (Continued)

e. **INTELLECTUAL PROPERTY (PATENTS/ROYALTIES/TRADEMARKS)**

☐ **NONE** (If "none", skip to Item f.)

FOR	ESTABLISHMENT	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW AND INDICATE INCOME RECEIVED
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

f. EXPERT WITNESS (Last 12 Months or under negotiation)

☐ **NONE** (If "none", skip to Item g.)

I appeared for or against the following listed establishment(s) and issue(s)

FIRM AND ISSUE	AMOUNT RECEIVED	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

g. SPEAKING/WRITING (Last 12 Months or under negotiation)

☐ **NONE** (If "none", skip to Item g.)

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED		DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
		HONORARIUM	TRAVEL		
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO

2. PAST FINANCIAL INTERESTS

a. To the best of your knowledge, do 1) you or any of your relative within the fourth (4th) civil degree, by affinity or consanguinity, 2) organization in which you serve as an officer, director, trustee, general partner, or employee have any past involvement with any policy determining activity of the office/agency/advisory body/committee:

☐ **YES** ☐ **NO** ☐ **NOT TO MY KNOWLEDGE**

b. If "Yes," describe involvement.

FIRM/PRODUCT	FINANCIAL INVOLVEMENT (e.g. contract/consultant)	ROLE	DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO

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3. OTHER INVOLVEMENTS (Other Kinds of Relationships) ☐ **NONE** (If "none", skip to Item 4.)

Using the list of products/firms/issues, identify anything that would give an "appearance" of a conflict which has not been disclosed above (e.g. involvement in a lawsuit, researcher initiated study, gift of research materials, etc.).

4. CERTIFICATION STATEMENT

I, _____ designated as _____ of the _____
(First Name, MI, Family Name) (Position/Designation, when applicable) (Name of Agency, Office, Bureau, Service, Hospital, or Unit)

do hereby declare on my honor that the above information is true and complete, to the best of my knowledge. If there are any changes, I will promptly notify you. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

My response contains ____ pages.

NAME AND SIGNATURE OF DECLARANT**DATE****CONFIDENTIALITY STATEMENT**

The primary use of this information is for review of the Public Health Ethics Committee (PHEC) to determine compliance with applicable conflict of interest with laws and regulations.

This confidential report will not be disclosed to any requesting person, unless authorized by law.

Falsification of information or failure to file or report of information required to be reported is subject to disciplinary action by the DOH.

FOR PHEC USE ONLY**NAME AND SIGNATURE OF REVIEWING OFFICIAL****DATE****COMMENTS OF REVIEWING OFFICIAL****IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES**