

Discussion Paper¹

**Public Health Ethics at the Centers for Disease
Control and Prevention (CDC)²:
Ensuring Health, Improving Trust**

The What, Why, and How of
Public Health Ethics at CDC

Prepared by the CDC Public Health Ethics Committee (PHEC)

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¹ This document is intended to generate discussion on the role of public health ethics at CDC. We view this as a living document that will evolve over time. All comments are welcome and should be sent to Drue Barrett, Chair of the Public Health Ethics Committee, DBarrett@cdc.gov.

² CDC refers to both CDC and ATSDR.

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1. What If? – Examples of Ethical Dilemmas at CDC

What if a food additive was noted to have previously unreported adverse effects? You undertake a study and the manufacturer of the food product wants to provide CDC with additional funds to conduct a larger and more definitive study. Should CDC accept the manufacturer's offer?

You are asked to prioritize limited research funds. One proposed project could provide information to impact the health of a large number of persons, while another would likely yield information which reduces a health disparity in a minority population. Which project should you fund?

You are called to provide emergency assistance by conducting surveillance activities in a disaster affected area. While collecting data, you have an opportunity to answer a research question about the effectiveness of one of the interventions being implemented. Should you undertake the research work or devote all of your time to the surveillance activities?

What if there is a sudden shortage of a widely used vaccine. Not everyone who wants the vaccine can receive it. On what basis will you decide who can get the vaccine and who cannot?

2. Introduction to Public Health Ethics

The situations described above are examples of ethical or values dilemmas that may arise for CDC employees in the process of carrying out their normal public health duties and responsibilities. In the past, these situations have been addressed informally by CDC program staff and supervisors using their best judgment and values, and often by seeking input from outside advisory groups. In order to more systematically address difficult ethical issues in program decision making, CDC has initiated a variety of public health ethics activities described in this document. This document discusses public health ethics in general and then describes the CDC Public Health Ethics Infrastructure and the process of requesting a public health ethics consultation.

2.1 What is public health ethics?

Public health ethics involves a systematic process to clarify, prioritize and justify possible courses of public health action based on ethical principles, values and beliefs of stakeholders, and scientific and other information.

Public health ethics can be subdivided into a field of study and a field of practice. As a field of study, public health ethics seeks to understand and clarify principles and values which guide public health actions. Principles and values provide a framework for decision making and a means of justifying decisions. Because public health actions are often undertaken by governments and are directed at the population level, the principles and values which guide public health can differ from those which guide actions in biology and clinical medicine (bioethics and medical ethics) which are more patient or individual-centered. The key values

and beliefs inherent in a public health perspective include the importance of community and the interdependence of human beings, the use of science as the basis for public health knowledge, and the right to resources necessary for health.³

As a field of practice, public health ethics is the application of relevant principles and values to public health decision making. In applying an ethics framework, public health ethics inquiry carries out three core functions, namely: 1) identifying and clarifying the ethical dilemma posed, 2) analyzing it in terms of alternative courses of action and their consequences, and 3) resolving the dilemma by deciding which course of action best incorporates and balances the guiding principles and values.

2.2 What public health ethics is NOT

Public health ethics is not about finding fault or assigning blame. It is principally about improving public health practice, particularly public health decision making at the program level. It is part of a larger set of more general ethics-related activities at CDC (see Appendix A) such as programs and policies related to maintaining and enforcing scientific integrity, addressing conflicts of interest or other employee conduct issues, and protecting human subjects in research. However, public health ethics differs from these other more general ethics activities because it is not oriented towards enforcement or assuring compliance with regulations, guidelines, or standards of employee behavior. Public health ethics has as its primary purpose to help better inform decision makers, whether managers or program staff, in resolving ethical dilemmas in public health, such as those described at the beginning of this document.

2.3 Why do we need public health ethics at CDC?

Rationales

The problems that CDC addresses are often complex, involving multiple risk factors, multiple stakeholders with different perspectives, values, and beliefs, and many different ideas on how to prevent or ameliorate health problems. There may also be incomplete scientific evidence or gaps in relevant public health laws on many issues resulting in a great deal of uncertainty about the best course of action. Although ethical decision making has always been integral to all CDC decision making, a systematic, deliberate ethical analysis as described in this document provides an added value. There are two main rationales for the systematic practice of public health ethics which capture the “value added” by this work:

- To make sound decisions which are most in agreement with public health and other societal values
- To help ensure that the decisions we make are supported by those who are affected by our actions.

Key Benefits

CDC’s public health ethics activities will result in benefits at both the individual and the organizational level and include:

- Increased capacity to recognize ethical issues
- Development of better analytical skills in ethics

³ APHA Code of Ethics. 2002. American Public Health Association. Available at <http://www.apha.org/programs/education/progeduethicalguidelines.htm>.

- Greater transparency in decision making
- Tools for resolution of conflicts
- Enhanced public trust
- Strengthened scientific integrity and professional excellence

3 The Ethical Foundation for the Practice of Public Health

This section will describe various theories, frameworks, models, value-sets, and criteria that an individual or a group of individuals could refer to when addressing an ethical dilemma.

3.1 Ethics theories and frameworks

Several ethics theories and frameworks have been developed to assist in the reasoning and decision making surrounding ethics issues. One of the most useful ways to categorize these theories and frameworks is by their relationship to the three essential components of any human action, namely the agent or persons doing the acting, the act itself, and the consequences of the act. Virtue theories are centered on the agent or actor, deontological theories are centered on the acts themselves, and teleological (or consequentialist) theories are centered on the consequences of human actions. These theories differ in that they judge the ethics of a situation primarily in terms of whether or not the agent has virtuous habits and reflects them in action, whether or not the act per se satisfies an obligation or duty, and whether or not good is achieved by the acts. Utilitarianism, an influential theory in public health, is a type of consequentialism. A selected reference list for those interested in obtaining more information on ethical theories and frameworks as well as public health ethics topics is attached in Appendix B.

3.2 Values and principles relevant for public health

In addition to these ethical theories and frameworks, principles and values have been developed and identified by organizations, professional societies, and other sources to help guide persons seeking to arrive at ethical decisions. No ethical theory or framework, and no set of values or principles, can provide singular definitive answers to ethical dilemmas. Rather, each theory, framework, or set of values or principles provides a particular perspective for addressing the problem at hand, and each perspective contributes particular strengths and limitations for ethical analysis of the problem. As indicated previously, the key values and beliefs inherent in a public health perspective include the importance of community and the interdependence of human beings, the use of science as the basis for public health knowledge, and the right to resources necessary for health.⁴ Other examples of values and principles relevant for public health ethics at CDC are:

CDC Core Values⁵

1. **Accountability** — As diligent stewards of public trust and public funds, we act decisively and compassionately in service to the people's health. We ensure that our research and our services are based on sound science and meet real public needs to achieve our public health goals.

⁴ APHA Code of Ethics. 2002. American Public Health Association. Available at <http://www.apha.org/programs/education/progeduethicalguidelines.htm>.

⁵ CDC's Mission. July 16, 2006. Centers for Disease Control and Prevention. Available at <http://www.cdc.gov/about/mission.htm>

2. **Respect** — We respect and understand our interdependence with all people, both inside the agency and throughout the world, treating them and their contributions with dignity and valuing individual and cultural diversity. We are committed to achieving a diverse workforce at all levels of the organization.
3. **Integrity** — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.

American Public Health Association (APHA) Code of Ethics⁶

The APHA's code of ethics is an explicit statement of ethical principles inherent to public health. This code is meant to clarify the distinctive elements of public health and the ideals of public health institutions.⁷ These principles are:

1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
2. Public health should achieve community health in a way that respects the rights of individuals in the community.
3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.
6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.
9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
11. Public health institutions should ensure the professional competence of their employees.
12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

3.3 Models for ethical decision-making

In identifying, analyzing, and resolving ethical and values dilemmas, public health ethics involves a multi-step process. Several inventories of the steps of ethical decision making have been produced which are similar conceptually even if they differ in the number and order of steps. Two such models are presented below and the steps are summarized graphically in

⁶ APHA Code of Ethics. 2002. American Public Health Association. Available at <http://www.apha.org/programs/education/progeduethicalguidelines.htm>

⁷ Thomas, et al. A code of ethics for public health. *Am J Public Health* 2002;92:1057-1059.

Appendix C.

Sample Models of Ethical Decision Making	
<i>Model #1⁸</i>	<i>Model #2⁹</i>
1. Identify the public health ethics issue	1. Recognize and identify ethical issues and specific ethical problems in the case.
2. Identify stakeholders and their values	2. Identify the key facts, establish important definitions, and gather other necessary information.
3. Formulate the facts and identify the information gaps	3. Identify professional ethical principles, standards of practice, and law relevant to the ethical issues of the case.
4. Generate and compare options	4. Identify the possible alternative courses of action, the ethical arguments for and against their implications, and their likely outcomes.
5. Decide and justify the decision	5. Choose the course that is best supported by the preceding analysis.
6. Act and evaluate	6. Evaluate the actions taken and their subsequent outcome.

3.4 Best practices for public health ethics

The practice of public health ethics involves ongoing efforts to specify, analyze, and resolve conflicts in values and principles, in the context of particular public health policies, practices, and actions. To the extent possible ethical public health decision making and actions adhere to the following best practices:¹⁰

- are open, honest, and transparent
- involve affected, informed, experienced and neutral individuals and representatives of communities;
- are interactive processes that attempt to balance the rights, values, interests, and needs of individuals and communities, the duties of federal agencies, and the obligations of public health professionals;
- acknowledge that reasonable people may differ in their values and beliefs and communities differ in their cultures, norms, governance, powers and resources;
- apply “what we know” (the best science, evidence, and management) to problem solving and solution building;
- address the economic, political, and organizational constraints to actions;
- identify and address competing values and interests and moral ambiguity;

⁸ Adapted from An Ethics Primer, Northwest Association for Biomedical Research. Available at www.nwabr.org.

⁹ Based on Heitman E. Using Cases In The Study Of Ethics. In: Bulger RE, Heitman E, Reiser SJ. The Ethical Dimensions of the Biological and Health Sciences, 2nd edition, New York:Cambridge University Press, 2002, pp. 349-52

¹⁰ Childress, et al. Public health ethics: Mapping the terrain. *J Law Med Ethics*; 2002: 170-178.

- are clearly described and timely, with procedures for input, review, appeal and re-consideration; and
- articulate the critical thinking and analysis leading to a decision or action

3.5 Criteria for evaluating conflicting values and principles

In public health practice and research, ethical dilemmas sometimes arise when public health goals conflict with other societal values, such as individual liberty and justice. For such situations, justificatory conditions have been proposed to assess the ethical warrant of the public health activity in question.¹¹ This set of justificatory conditions can be used to compare the relative ethical warrant of alternative public health policy or program options:

- Effectiveness: The policy or program that infringes one or more values or principles is likely to achieve the intended public health goal.
- Proportionality: The probable public health benefits of the policy or program will outweigh the infringed values or principles.
- Necessity: The policy or program is necessary to realize the public health goal that is sought.
- Least infringement: The public health policy or program minimizes the infringement of other values and principles.
- Public justification: When public health actions will infringe one or more values or principles, the infringement must be adequately explained and justified by public health agencies and staff, especially to those affected by the infringement.

4. Vision, Mission, and Goals of CDC’s Public Health Ethics Activities

The CDC Public Health Ethics steering committee has developed the following vision statement, mission statement, and goals to help define our activities.

Vision: Ensuring health, improving trust.

Mission: The mission of CDC’s public health ethics activities is to provide leadership in public health ethics at CDC and to work with CDC staff to explicitly and systematically integrate the tools of ethical analysis into decisions and day-to-day activities across CDC.

Goals: The organizational and individual professional level goals of the public health ethics activities include:

- Organizational awareness of ethical issues and dilemmas.

¹¹ Childress, et al. Public health ethics: Mapping the terrain. *J Law Med Ethics*; 2002: 170-178.

- CDC’s organizational atmosphere that expects, develops, and holds staff accountable for informed and critical thinking, ethical analysis, well reasoned and justifiable decisions and actions, and excellent communications.
- The application of ethical analysis to CDC’s public health science, practice, programs, and policies.
- Professional and agency credibility and trust.
- Professional awareness of ethical issues and dilemmas.
- Awareness, knowledge, skills, and confidence in identifying, analyzing, and resolving public health ethics issues.

5. Organizational Aspects of Public Health Ethics at CDC

In early 2005, CDC initiated a formal infrastructure to strengthen leadership in public health ethics. The main components of this public health ethics infrastructure are the Ethics Subcommittee of the Advisory Committee to the Director, CDC, the CDC Public Health Ethics Committee, and the CDC Public Health Ethics Coordinator within the Office of the Chief Science Officer (OCSO) (see Appendix E).

The Ethics Subcommittee of the Advisory Committee to the Director, CDC (Ethics Subcommittee, ACD) was established to provide counsel to the CDC Director on a broad range of public health ethics questions and issues arising from programs, scientists and practitioners, and to support CDC in the development of internal capacity to identify, analyze, and resolve ethical issues. The Ethics Subcommittee, ACD is composed of academic and professional ethicists from outside CDC.¹²

The CDC Public Health Ethics Committee (PHEC) is composed of public health ethics leads and alternates from each of CDC’s national centers (NC¹³) and the National Institute for Occupational Safety and Health (NIOSH), selected offices within coordinating centers and the CDC Office of the Director, liaisons from a variety of CDC scientific workgroups, and other interested CDC staff.¹⁴ The mission of PHEC is to provide leadership in public health ethics at CDC and to work with CDC staff to integrate the tools of ethical analysis into decisions and day-to-day activities across CDC. In order to accomplish its mission, PHEC has established a Steering Group and three subcommittees (Framework and Policy Subcommittee, Education

¹² The membership list of the Ethics Subcommittee, ACD is available at <http://intranet.cdc.gov/od/ocso/ethics/committee/jointMeetings/>.

¹³ Subsequent use to NC refers to CDC national centers and NIOSH. Procedures described for NC public health ethics leads apply to public health ethics leads from coordinating offices and offices of the CDC Office of the Director represented on PHEC.

¹⁴ The membership list of PHEC is available at <http://intranet.cdc.gov/od/ocso/ethics/committee/phec/>.

Subcommittee, and Consultation Subcommittee). In addition, one of the members of the PHEC Steering Group serves as the PHEC liaison to the Ethics Subcommittee, ACD.

The PHEC Steering Group is composed of chairs and co-chairs of the PHEC subcommittees and selected other members of PHEC who were chosen because of the prior expertise in public health ethics. PHEC Steering Group members meet monthly and serve as the core leaders for PHEC.

PHEC subcommittees are composed of PHEC members and, as noted above, PHEC subcommittee chairs and co-chairs serve on the PHEC Steering Group. The subcommittees meet as needed and work on specific projects. Products developed by PHEC subcommittees are reviewed and approved by the PHEC Steering Group before they are presented to the wider PHEC membership. The PHEC subcommittees and their functions are:

- **Framework and Policy Subcommittee:** Develop a conceptual framework, infrastructure, and implementation plan for public health ethics at CDC.
- **Education Subcommittee:** Develop and implement a plan for public health ethics education for PHEC and CDC staff.
- **Consultations Subcommittee:** Establish guidelines for public health ethics consultations; serve as a resource and participate in consultations, identify emerging issues.

The NC public health ethics lead serves as the NC representative on PHEC and provides leadership in public health ethics within their NC. This includes organizing or leading ethics trainings for NC level staff, identifying, referring or addressing public health ethics issues within their NC, and bringing ethics issues to the attention of PHEC or the CDC Public Health Ethics Coordinator. NC public health ethics leads are encouraged to establish NC level public health ethics teams.

The NC public health ethics team includes the NC public health ethics lead and alternate(s) and other interested staff. They provide public health ethics leadership within the NC and address public health ethics issues within the NC.

The CDC Public Health Ethics Coordinator serves as the Chair of PHEC and the Designated Federal Official for the Ethics Subcommittee, ACD. This position serves as the main point of contact for public health ethics issues at CDC.

6. Public Health Ethics Education Program at CDC

The PHEC Education Subcommittee, in collaboration with the PHEC Steering Group, other PHEC subcommittees, the Ethics Subcommittee, ACD and other groups across CDC (e.g.,

Health and Human Rights Workgroup) plays the following roles in developing CDC capacity in public health ethics:¹⁵

- Assessing CDC resources, needs and competency relating to public health ethics.
- Planning educational programs in public health ethics for CDC staff.
- Conducting (competency-based) trainings, workshops, seminars.
- Evaluating public health ethics educational and training activities.
- Collaborating with other CDC groups (and committees) on public health ethics- related educational activities.

The goals of the PHEC Education Subcommittee are to:

- Develop competency among PHEC committee members.
- Develop competency among the broader CDC staff.
- Develop, coordinate, and conduct educational and training activities for CDC staff and partners.
- Support and conduct research on public health ethics.
- Evaluate CDC public health ethics activities.

7. The Public Health Ethics Consultation Process at CDC

A public health ethics consultation may be required when a component of CDC identifies an ethical concern and wishes to obtain guidance on addressing the concern. Ethical concerns develop when there is uncertainty or conflict about values. Public health ethics consultations involve a systematic approach to clarifying the issue, determining the pertinent ethical principles and values, identifying possible alternative courses of action and ethical arguments for and against each proposed action, recommending a strategy, and evaluating the outcome. These are steps in ethical decision making described in section 2.4.

There are several different reasons that a public health consultation may be requested. One scenario is when a CDC unit is preparing to implement a new program or policy and wishes to obtain a broader perspective on the issues before implementation. A second scenario is when there are questions about how to best respond to new or unexpected data. A third scenario would be when a CDC unit wishes assistance from a group of ethicists in planning how to address a possible event or outbreak. A fourth scenario would be when one or more members of the CDC community believe that there are ethical concerns about a course of action being planned or taken by CDC. Regardless of the reason for requesting a public health consultation, the goal of the consultation is to consider the request from different perspectives and develop a set of alternatives and recommendations for the program to consider.

7.1 Public health ethics consultation principles

The PHEC has identified the following guiding principles for the conduct of public health ethics consultations:

¹⁵ More information about PHEC's Education Program can be found in the Education Strategic Plan: <http://intranet.cdc.gov/od/ocso/ethics/startConsultation.htm#>

- Public health ethics questions and consultation requests should be addressed at the lowest organizational level in collaboration with the NC public health ethics lead.
- While it may be necessary to address some public health ethics issues with an urgent consultation, programs and PHEC members should be proactive in identifying potential issues requiring public health ethics consultations to allow time for adequate consideration of the ethical questions.
- PHEC members with an interest in or responsibilities for topics brought to the CDC Public Health Ethics Coordinator or the PHEC Consultations Subcommittee should participate as partners on workgroups established to develop the charge, background materials, or other actions needed. This is especially important if consultation by the Ethics Subcommittee, ACD is requested.
- Because many components of CDC routinely address ethical issues, some ethical issues may more appropriately be addressed entirely or in part by another activity at CDC. Consultation requests should be considered for referral to or inclusion of staff from other ethics-related offices if the request includes:
 - Regulatory compliance issues, including human research protections, scientific conduct, conflicts of interests, OMB regulations
 - Staff conduct and performance issues
 - Information and computer security
 - Privacy issues, including the Health Insurance Portability and Accountability Act (HIPAA)
- Active involvement of PHEC members or the CDC Public Health Ethics Coordinator in responding to a consultation request would be indicated if the request deals with one of the following priority areas:
 - Cross-cutting issues that relate to the interests or responsibilities of more than one NC
 - Highly sensitive issues, such as those related to terrorism, that are not addressed at the NC level
- Involvement of the Ethics Subcommittee, ACD would be indicated in the following circumstances:
 - When the NC requests a consultation with the Ethics Subcommittee, ACD. Requests should be addressed to the CDC Public Health Ethics Coordinator who in consultation PHEC Steering Group lead will determine the appropriateness of engagement of the Ethics Subcommittee, ACD.
 - When the issue is such that an internal consultation may give the appearance of a conflict of interest.
 - When the CDC Public Health Ethics Coordinator, OCSO leadership or CDC Office of the Director determines that an issue should be taken to one or more of the members of the Ethics Subcommittee, ACD.

- The implementation of the recommendations of the consultation product is at the discretion of the program. Public health ethics consultations at any level are only consultations and the products are recommendations only. The program must balance a number of factors in making any decision and the consultation product is only one of the factors involved.
- In situations where the consultation request comes from an individual or small group of individuals, the NC public health ethics lead and team will exercise discretion in obtaining information about the request, and attempt to protect the confidentiality of the requestor(s). However confidentiality can not be guaranteed. In a small community (such as a branch or division) the identity of individuals with specialized knowledge or strong opinions on certain issues may be readily discerned. Additionally when the people making the request have already stated their concerns to management or in public venues there is no confidentiality to protect.

7.2 Public health ethics consultation administrative procedures

- The first point of contact for most consultation requests is the NC public health ethics lead or a member of the NC public health ethics team (if one has been established). The NC public health ethics lead clarifies the issue through discussions with the requestor, with the NC Associate Director for Science, and with other NC leadership as needed. NC leadership is encouraged to give support and authority to the public health ethics leads to conduct consultations. The public health ethics lead must be aware of the sensitivity of the requests and exercise discretion in sharing details of the request. Wherever possible the identities of individuals requesting an initial consultation should be protected by the NC public health ethics lead and all parties to the consultation.¹⁶
- PHEC members, PHEC Steering Group members, and PHEC subcommittees members will refer all questions concerning NC-specific issues to the appropriate NC public health ethics lead. If the CDC Public Health Ethics Coordinator is contacted regarding a NC-specific request, the Public Health Ethics Coordinator will contact the NC public health ethics lead for his/her input on the need for OCSO involvement in the consultation.
- All requests for consultations with the Ethics Subcommittee, ACD should be referred to the CDC Public Health Ethics Coordinator and the requestor should complete a Public Health Ethics Consultation Request Form (see Appendix E) specifying the nature of the request and timeline. The CDC Public Health Ethics Coordinator will notify the PHEC Consultation Subcommittee Chair, the PHEC Steering Group, and other NC public health ethics leads who may have an interest in the topic area. The CDC Public Health Ethics Coordinator in consultation with the PHEC Steering Group will prioritize topic areas for engagement of the Ethics Subcommittee, ACD if there is insufficient time or resources to address multiple requests.

¹⁶ Employees are protected from retaliation for raising issues under the Notification and Federal Employees Anti-Discrimination and Retaliation Act of 2002 (No FEAR Act). <http://www.commerce.gov/NoFEARAct.pdf>

- The NC public health ethics lead will maintain records that document NC-specific public health ethics consultation requests, progress, and completion of the response. A summary of NC specific consultation activities will be reported quarterly to the CDC Public Health Ethics Coordinator. These reports will be reviewed by the PHEC Steering Group. Selected issues may be shared with PHEC members to promote sharing of information and the development of ethical analysis skills. The CDC Public Health Ethics Coordinator will maintain records of all cross-cutting public health ethics consultations and consultations involving the Ethics Subcommittee, ACD.
- All costs for conducting NC-specific consultations will be borne by that NC. Some of the costs for conducting cross-cutting consultations (as determined by OCSO) may be borne by OCSO. If consultations involve members of the Ethics Subcommittee they should be compensated at the rate of \$250 per day or \$31.25 per hour if the service is less than a full day, when consultations are being conducted. Compensation is not generally provided for preparation time.
- To prevent expenditure of time and resources on questions that do not impact activities, all requests for public health ethics consultations including one or more members of the Ethics Subcommittee, ACD must be approved by program officials who have responsibility for that program and must be in writing. The clearance chain may differ for each NC, but at a minimum should include the Division Associate Director for Science, the Division Director, and the NC Associate Director for Science. NC public health ethics leads should work closely with their Division and NC Associate Directors for Science to determine the appropriate clearance chain. Approval of a request for a consultation does not imply agreement with or endorsement of any position related to the request, but does indicate a willingness of the organization to thoughtfully consider the results of the consultation in decisions or activities. If the request for consultation is not approved, the rationale for not pursuing the consultation should be documented in the NC public health ethics consultation quarterly report.

7.3 Public health ethics consultation products

At a minimum the product of a consultation request should consist of a written statement describing the request and the resolution or recommendation(s) resulting from the consultation. If the consultation includes one or more of the members of the Ethics Subcommittee, ACD of the Advisory Committee to the Director, CDC, there will also be written documentation of the charge to the ethicist(s), the procedures for conducting the consultation, and a summary of the discussion leading to the suggestions.

The written record of the consultation will be forwarded to the NC Director, the NC Associate Director for Science, the NC public health ethics lead, and the person making the request. A copy will also go to the CDC Public Health Ethics Coordinator for the PHEC files. Copies may also be shared with the PHEC Steering Group, PHEC, the Ethics Subcommittee, ACD, the CDC Chief Science Officer, or other CDC and NC management.

7.4 Evaluation procedures

The CDC Public Health Ethics Coordinator and the PHEC Steering Group will review consultation requests and outcomes periodically. They will determine if there are recurring issues that indicate a need for educational activities or for a cross-NC consultation to address issues present in multiple NC. The CDC Public Health Ethics Coordinator will contact a subset of the programs bringing consultation requests to determine how the programs viewed the consultation process and whether procedures need to be modified to improve the process. Annually a report of consultations will be presented to the CDC Associate Director for Science and the CDC Chief Science Officer.

Appendix A: Examples of CDC Ethics-Related Programs and Activities

Appendix A describes activities that are generally placed under the label, ethics, at CDC. The activities are categorized into efforts that emphasize regulatory compliance, social advocacy, or public health ethics

Regulatory Compliance

Scientific Integrity

The Department of Health and Human Services' Office of Research Integrity (ORI) promotes integrity in biomedical research supported by the Public Health Service at about 4,000 institutions worldwide. ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through educational, preventive, and regulatory activities. CDC's Associate Director for Science serves as the Agency Research Integrity Liaison Officer, the Director of the Office of Scientific Regulatory Services (OSRS) serves as the Agency Intramural Research Integrity Liaison, and the Director of the Office of Public Health Research (OPHR) serves as the Agency Extramural Research Integrity Officer. For more information, see <http://ori.dhhs.gov>.

Ethics Program Activity Office

The CDC Ethics Program Activity Office is responsible for interpreting standards of conduct regulations, reviewing financial disclosure reports, and offering continuing ethics training and counseling services to ensure that CDC employees avoid situations that could violate regulatory ethics laws and undermine the public's trust in Government. Employees are subject to statutes and regulations commonly referred to as "ethics" standards. The conflict of interest statutes at Chapter 11 of Title 18, United States code, prohibit a Federal employee from engaging in certain types of activities that would place the employee's own personal interests above the Federal Government's interests. The standards of conduct regulation, Code of Federal Regulations Part 2635, establish principles of ethical conduct for employees of the executive branch. For more information, see <http://intranet.cdc.gov/od/ethics/aboutepa.htm>.

Human Research Protection Office

The mission of the Human Research Protection Office (HRPO) within the Office of the Chief Science Officer is to lead the agency in protecting the rights and welfare of those who participate in CDC-sponsored public health research, through the practices of investigators, program leaders, and the CDC Institutional Review Boards (IRBs), and through relationships with external partners. All research involving human participants that is conducted or supported by CDC must comply with the HHS Policy for Protection of Human Research Subjects (45 CFR part 46). This includes research conducted by CDC employees or supported by CDC through funding or provision of other tangible support, whether conducted inside or outside the United States. Unless exempt, all such research must be approved by an IRB prior to the start of the research. HRPO facilitates the work of the IRB and provides assistance and training for CDC staff engaged in research involving human participants. Clinical investigations that involve the use of drugs, biologics, or devices—whether unlicensed or used outside standard medical

practice—are subject to IRB review and approval under 21 CFR parts 50 and 56. For more information, see <http://intranet.cdc.gov/od/ocso/osrs/hrpo.htm>.

Authorship Policy

CDC's Authorship Policy provides procedures and guidelines to assist CDC authors in developing and preparing information products for publication. The policy outlines the minimum basis for authorship on information products and describes universal, baseline procedures that are applicable in all contexts within CDC. The policy also outlines roles and responsibilities and the copyright rule for federal employees. A section on ethical considerations discusses important issues such as redundant or duplicate publications, disclosure of conflicts of interest, and plagiarism. For more information, see http://aops-mas-iis/policy/Doc/333_695.htm.

Intellectual Property

The Technology Transfer Office (TTO) within the Office of the Chief Science Officer provides leadership and expertise to promote and affect the timely transfer of knowledge and technology for development of products and processes that improve public health. The TTO staff is responsible for the patenting and licensing of CDC inventions. Further, TTO's Licensing Specialist together with Centers/Offices. Technology Transfer Representatives (TTR) negotiates the Centers' Cooperative Research and Development Agreements (CRADAs) and Biological Materials Licensing Agreements (BMLAs). Issues of ethical concern may include conflicts of interest (financial), fair access (ensuring commercial partners have fair access to inventions), and the use of the CDC logo (by commercial companies with whom the CDC has partnerships). For more information, see <http://intranet.cdc.gov/od/ocso/tto.htm>.

Computer Security Awareness

Information Technology Services Office (ITSO) is responsible for providing information technology (IT) services in thirteen functional areas - desktop computing support, directory services, e-mail, helpdesk, infrastructure software, IT security, networking, data center services, office automation, remote access, server management, video conferencing, and telecommunications. ITSO has developed service level agreements for these functional areas. Some ethical concerns include computer passwords, data protection, CDC software licensing, telephone security, Blackberry information, emergency preparedness, inappropriate personal use of computers, and email and spam protection. For more information, see <http://intranet.cdc.gov/itso/>.

Information Security

The mission of the Office of the Chief Information Security Officer (OCISO) is to provide information security protections commensurate with the risk and magnitude of harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of information collected or maintained by or on behalf of the CDC and information systems used or operated by the CDC or CDC contractors or other organization on behalf of the CDC. OCISO administers the Security Awareness Training, accessed only through the CDC intranet and also oversees policies related to inappropriate personal use of computers. This site is located at

<http://intranet.cdc.gov/ecp/training.asp> (under CIO Training and Education Programs, click on 2005 Security Awareness Training). The mission and responsibilities of the OCISO are statutorily defined in Title III of the Electronic Government Act of 2002, Chapter 35 of Title 44, United States Code. For more information, see <http://intranet.cdc.gov/ociso/>.

Social Justice

Health and Human Rights Workgroup

The CDC Health and Human Rights Workgroup (HHRW) seeks to educate and train public health professionals about health and human rights (HHR) principles and the methods for incorporating these principles into public health practice. HHRW activities include but are not limited to the following: hosting seminars and workshops, co-sponsoring conferences on HHR, developing a compendium of HHR resources, and collaborating with other groups on related HHR issues. For more information, see <http://intranet.cdc.gov/hhrw/>.

Office of Minority Health and Health Disparities

The Office of Minority Health and Health Disparities (OMHD) within the Office of Strategy and Innovation aims to accelerate CDC's health impact in the U.S. population and to eliminate health disparities for vulnerable populations as defined by race/ethnicity, socio-economic status, geography, gender, age, disability status, risk status related to sex and gender, and among other populations identified to be at-risk for health disparities. To carry out its mission, OMHD promotes minority health to eliminate racial and ethnic health disparities; promotes health and the prevention of disease in Indian Country (i.e., American Indian and Alaska Native communities, their sovereign governments and other institutions in the U.S.); and develops CDC-wide health disparities elimination strategies, policies, goals, and programs. For more information, see www.cdc.gov/maso/OSIfs/pdf.

CDC/ATSDR Minority Initiatives Coordinating Committee

The CDC/ATSDR Minority Initiatives Coordinating Committee (CAMICC) coordinates all the Health and Human Services (HHS) departmental minority health initiatives within CDC/ATSDR, including activities which target all racial and ethnic groups. The committee also provides guidance and policy direction for minority health initiatives, serves as an advisor on matters related to minority health, and provides leadership in developing and implementing plans to improve minority health nationally. The committee is comprised of representatives from Centers. For more information, see <http://intranet.cdc.gov/od/omh/>.

Ombudsman Office

The Ombudsman Office serves as a resource for all non-contract employees regarding concerns not addressed through other program offices. The office is intended to supplement and not to replace or duplicate any existing procedures or venues for airing grievances or complaints handled by other offices. Its operations will be independent of the usual administrative structure at CDC. In addition, there is an emphasis on non-adversarial problem-solving options that help avoid future disputes. For more information contact the office at 404-498-6680.

Public Health Ethics

In early 2005, CDC initiated a formal infrastructure to strengthen leadership in public health ethics. The main components of this public health ethics infrastructure are the CDC Public Health Ethics Committee (PHEC), the Ethics Subcommittee of the Advisory Committee to the Director, CDC, and the CDC Public Health Ethics Coordinator within the Office of the Chief Science Officer. The mission of PHEC is to provide leadership in public health ethics at CDC and to work with CDC staff to integrate the tools of ethical analysis into decisions and day-to-day activities across CDC. For more information see, <http://intranet.cdc.gov/od/ocso/ethics/>

Appendix B: Selected References Relating to Public Health Ethics

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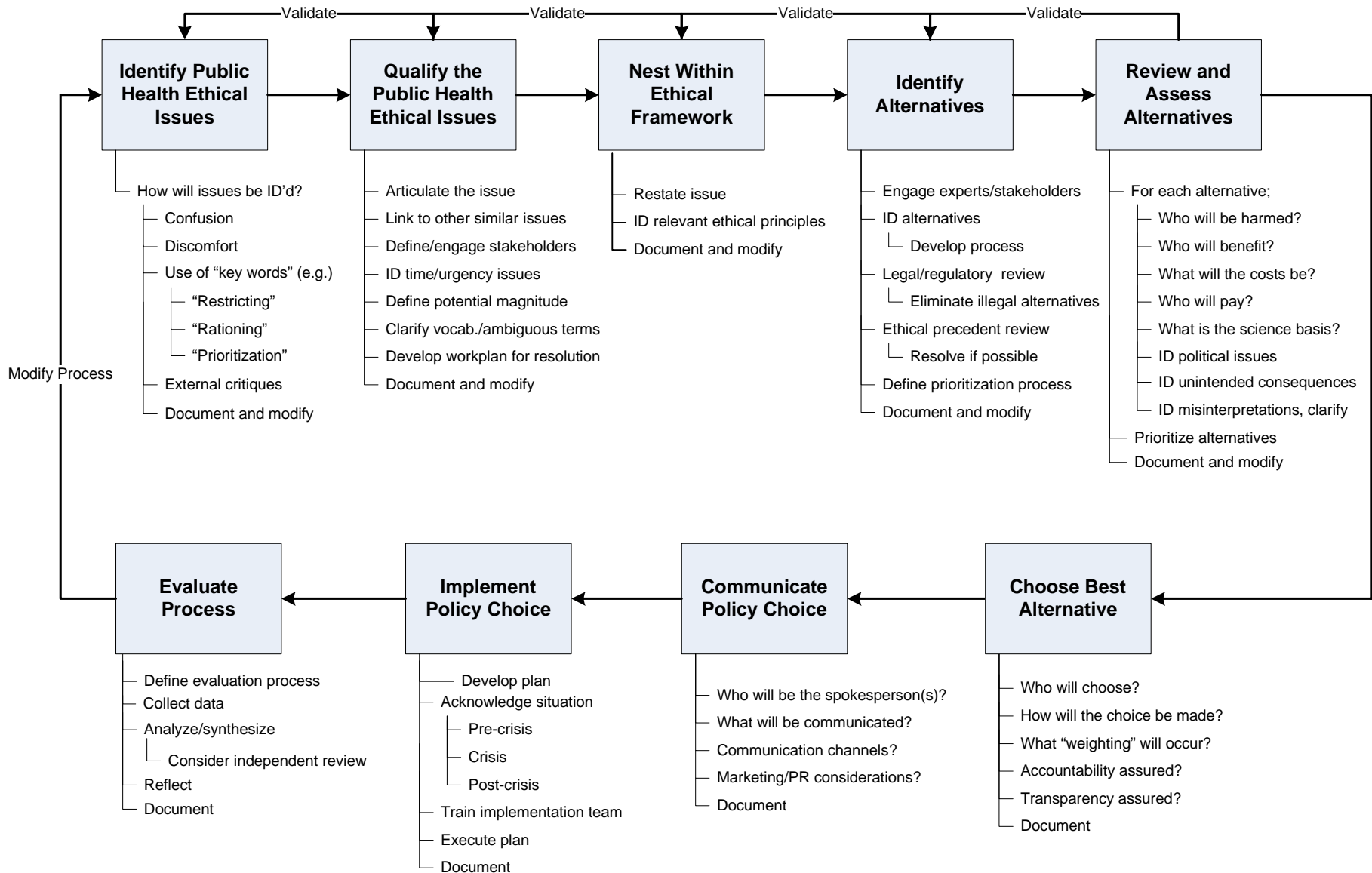
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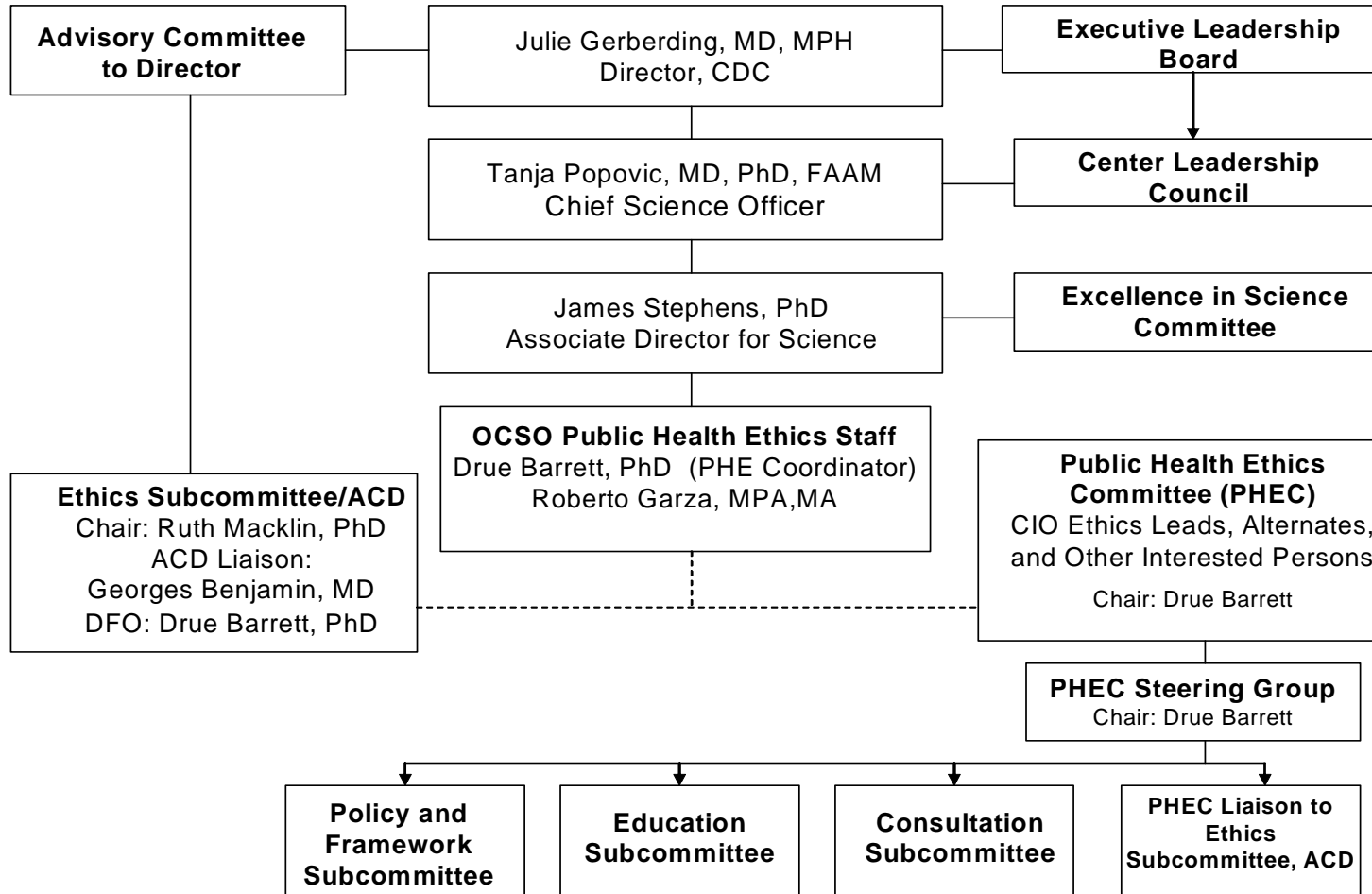
Appendix C: Steps in Public Health Ethical Decision-Making

Steps in Public Health Ethical Decision-Making



Appendix D: CDC Public Health Ethics Infrastructure

CDC Public Health Ethics Infrastructure



Appendix E: Public Health Ethics Consultation Request Form

Request ID: _____

Date of Request: _____

Type of Assistance Requested:

Urgency of Request:

- Forum for discussion
- Guidance from the Public Health Ethics Committee
- Guidance from the Ethics Subcommittee, ACD*
- Other

- Routine
- Urgent, immediate action requested

Desired Time Frame:

Requestor's Name and Contact Information:

Name: _____ Position Title: _____

Mailing Address: _____ Phone: _____

_____ Email: _____

Person Contacted Regarding the Request:

- Public Health Ethics Lead
- Public Health Ethics Committee member

Name: _____

Others Involved in Vetting the Request:

Name: _____

Name: _____

Title: _____

Title: _____

Brief Description of the Issue and the Ethical Concerns:

Steps Already Taken to Resolve the Issue:

Stakeholders – Please list and indicate if they have been involved in identifying the ethical issues and/or questions.

Please identify other persons or references that may be helpful to the Consultation Team (Optional)

Suggested internal or external members for the Consultation Team (Optional):

Date Request Forwarded to the NC PHEC:

Recommendation of the NC Public Health Ethics Committee:

Accept the Request

Reject

Reasons for Rejecting the Request:

5. Approvals/Signatures:	Date:	Remarks:
Requestor:		
Division ADS:		
Division Director:		
NC Science Officer:		
NC Director:*		

* All requests for public health ethics consultations including one or more members of the Ethics Subcommittee, ACD must be approved by a program official with responsibility for that program.