APPLYING THE PUBLIC HEALTH CODE OF ETHICS TO THE FEDERAL WORKFORCE

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A dissertation submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Public Health in the Gillings School of Global Public Health

Chapel Hill
2010

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ABSTRACT

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Applying the Public Health Code of Ethics to the Federal Workforce
(Under the direction of Edward Brooks, DrPH)

Although the public health code of ethics was published in 2002, it has not been widely

disseminated or formally adopted by the two largest public health institutions within the U.S.

Public Health Service —the Centers for Disease Control and Prevention (CDC) and the

National Institutes of Health (NIH). In order to determine the applicability and feasibility of

implementing the public health code of ethics within the federal government, this study

examines the ethics programs in the two largest public health agencies; how the current

ethics programs at these agencies compare with the principles in the public health code of

ethics; and where benefits to adopting the code are identified, how barriers to implementing

it can be addressed.

Results from this study revealed that both agencies are addressing most of the principles in

the code of ethics with their current practices, policies, and ethics activities. CDC officials

interviewed for this study had a high degree of familiarity with the code and indicated that it

is an integral part of the agency's public health ethics program. The code of ethics is a tool

that aligns with the CDC's mission and is well-suited for formal adoption by the agency. The

NIH has an ethics program that is appropriately geared toward research ethics. While there

would be little benefit from NIH adopting the public health code of ethics agency-wide, NIH

should consider the code for the segment of its workforce that designs, manages, and evaluates public health education, campaigns, and research programs. In addition, the Public Health Leadership Society should clarify the rationale for the public health code of ethics, thereby extending its reach.

There is a role for the public health code of ethics in the federal workforce. The CDC should adopt the code for use agency-wide and the NIH should use the code with the segment of its employees doing direct public health outreach and research in communities. In addition, the Public Health Leadership Society should take a more active role in articulating the need for the code and engage in activities that will facilitate wider awareness and use of it.

Dedication

To Steven Peil, my partner in all things big and small

To Laurie Center and Michael Center, my first and best teachers

Acknowledgements

I am grateful to many who supported, inspired, and encouraged my doctoral studies. In particular, I acknowledge:

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LIST OF ABBREVIATIONS

APHA	American Public Health Association
ATSDR	Agency for Toxic Substance and Disease Registry
CDC	Centers for Disease Control and Prevention
COPR	Council of Public Representatives
CRS	Congressional Research Service
GAO	Government Accountability Office
HHS	Department of Health and Human Services
NIMHD	National Institute on Minority Health and Health Disparities
NIH	National Institutes of Health
PHLS	Public Health Leadership Society
PHS	U.S. Public Health Service
REACH	Racial and Ethnic Approaches to Community Health

CHAPTER 1: INTRODUCTION

Leaders in public health have undertaken an effort to further "professionalize" the field in several

ways. This movement has included activities such as identifying and promoting a common set

of competencies for the public health workforce, marketing a national credentialing examination

to test for mastery of several core competencies, proposing that public health professionals be

certified to engage in certain core activities, and establishing common principles of the ethical

practice of public health, referred to in this study as the "public health code of ethics." The

public health code of ethics was published in 2002, but has not been widely disseminated or

formally adopted by the largest public health institutions—the U.S. federal agencies with public

health missions. A large segment of the public health workforce is employed or funded by the

federal agencies that comprise the U.S Public Health Service (PHS). Employees in the PHS

agencies are subject to a legislated code of ethical behavior which applies to all employees of the

Executive Branch of the federal government. In order to determine the applicability and

feasibility of implementing the public health code of ethics within PHS agencies—and in

particular the two largest agencies within the PHS—it is important to consider three key

questions:

1. **In the context of the 12 principles of the public health code of ethics, what are the current practices of the National Institutes of Health and the Centers for Disease Control and Prevention, the two largest federal public health agencies?** This will include identification of the areas that are currently well-covered as well as the gaps. It will also define what additional benefit the code of ethics can provide, over and above the current mandated ethical standards.

2. **To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?** This will include an exploration of why the code of ethics has not been adopted by the agencies as well as any perceived barriers to doing so.

3. **If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?**

United States Public Health Service Agencies

Figure 1: United States Public Health Service Agencies

Agency for Health Care and Research Policy

Agency for Toxic Substances and Disease Registry

Centers for Disease Control and Prevention

Food and Drug Administration

Health Resources and Services Administration

Indian Health Service

National Institutes of Health

Substance Abuse and Mental Health Services Administration

The United States Department of Health and Human Services (HHS) is the federal entity charged with protecting the health of Americans and providing essential human services. This Executive Branch department is comprised of eleven divisions which carry out activities in the areas of health and human services. Eight of the divisions combine to form the U.S. Public Health Service (PHS) and represent the majority of the U.S. government's investment in health research, services, funding, and support. The PHS has a workforce of approximately 56,000 people across the country and a combined annual budget of approximately $52 billion.[1] Employees within the PHS must conduct their work according to the standards of ethical conduct mandated for Executive Branch employees.[2]

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[1] Analysis of data from United States Public Health Service, Department of Health and Human Services.

[2] The *Standards of Ethical Conduct for Employees of the Executive Branch* is mandated under 5 C.F.R., Part 2635.

While the PHS includes a total of eight agencies which conduct some public health-related work, the scope of this study includes the two largest agencies within the PHS: the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). These agencies employ or fund the majority of the federal public health workforce and represent the greatest federal financial investment in public health research and programs. The NIH had an annual budget of $29 billion in fiscal year 2008 and a workforce of over 18,000 people, and CDC, whose budget in fiscal year 2008 was $6.4 billion, employs approximately 15,000 staff and contractors. Outside the scope of this study are other offices and agencies within HHS with public health-related missions— such as the Office of Public Health Preparedness and the Office of the Surgeon General. While the NIH and CDC do not represent the universe of federal public health workers, they are major employers of the public health workforce and also have a role in providing funding and support to the states and to academic communities for public health activities and research. If the field of public health is moving to establish a common code of ethics, it should fill gaps in current practices and be compatible with the ethical standards legislated for federal employees in the Executive Branch, such as those within the NIH and CDC.

The Public Health Code of Ethics

In 2002, the Public Health Leadership Society published the *Principles of the Ethical Practice of Public Health,* which includes twelve principles that make up the public health code of ethics (see Figure 2) and a set of eleven values and beliefs that underlie the code (Public Health Leadership Society, 2002). The Public Health Leadership Society later developed a companion piece entitled *Skills for the Ethical Practice of Public Health* which provides guidance on moving the public health code of ethics into practice (Thomas, 2004). The work to develop the

public health code of ethics was funded in part by the CDC. The code was adopted by the American Public Health Association (APHA) in 2002 and has been endorsed by several public health organizations.

There are two features of the public health code of ethics that hint at its potential to be used in conjunction with the mandated standards, both of which are described by Dr. James Thomas, an author of the code of ethics, in his on-line lecture and learning modules on public health ethics (Thomas, accessed October, 2007 and October, 2010)(Thomas, accessed October, 2007 and October, 2010). First, the code of ethics was written with a focus on public health agencies rather than on individuals, a focus that parallels the emphasis of public health on the health and well being of populations rather than individuals. It was designed to be adopted by institutions to provide guidance for the ethical practice of public health. Second, Thomas describes the public health code of ethics as being "aspirational"—articulating a set of broad standards to which the field should aspire. In contrast, the *Standards of Ethical Conduct for Employees of the Executive Branch* which governs federal employees is a "prescriptive" set of standards that dictates specific behaviors and gives a detailed set of behavioral guidelines for a range of situations. The distinctions between the code of ethics and the mandated standards indicate the potential for the two to dovetail nicely if used together to provide both broad concepts of ethical conduct for the practice of public health at the agency level with more specific guidelines for individual conduct in specific situations or employees of the Executive Branch of the government.

Figure 2: The Twelve Principles of the Ethical Practice of Public Health

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.

In addition, within the federal workforce, there are examples of employees in other fields—such as physicians, other health care providers, and military personnel—who work for the federal government and are bound by both a professional oath or code of ethics and a mandated set of standards as would be the case for federal public health workers if the public health code of ethics is adopted by federal agencies. However, one key difference is that the public health code of ethics is designed to guide the behavior and practice of institutions, while many other professional codes of ethics are aimed at guiding an individual's behavior for ethical practice in a given field.

The NIH and CDC are entrusted with the largest budgets in the Public Health Service to carry out and provide funding for a substantial portion of the country's public health research and activities. In addition, these agencies employ the majority of the federal public health workforce. It should follow that any code of ethics intended for public health institutions should be carefully considered by those in these agencies charged with developing and maintaining their ethics programs and examined for elements that may align with each agency's mission, but may not be reflected in its current ethics programs. This study reviews the current ethics practices and activities at CDC and NIH, assesses the extent to which the code's principles align with the agencies' missions and current ethics practices, assesses barriers to adopting the code, and describes the process for making changes to the ethics programs at CDC and NIH if gaps are identified.

CHAPTER 2: REVIEW OF THE LITERATURE

Before a study of how the public health code of ethics could be applied to the federal workforce can begin, it is important to ascertain whether the code of ethics is in conflict with the ethics rules that are legally required for federal workers. This review of the literature is designed to address the question: ***Is the public health field's movement to establish a public health code of ethics compatible with and distinct from the mandated standards of ethical behavior in place for employees within the U.S. Public Health Service?*** Specifically, the review will address: 1) whether the code of ethics is compatible with mandated ethical standards such that the two would not be in conflict, and 2) whether it is distinct from the mandated ethical standards such that it could potentially fill gaps in the agencies' current ethics programs and policies.

Scope and Methodology

The goal of this review is to search for all relevant sections of ethics legislation governing PHS employees and all published congressional (Legislative Branch) reports and studies of how PHS agencies have implemented the ethics legislation. The purpose of reviewing this literature is to address whether and to what extent the proposed public health code of ethics is compatible with and is distinct from the standards for ethical behavior legislated for employees in the Public Health Service, and therefore could potentially add value to that segment of the workforce. In

addition, the review of literature will assess whether and to what extent the use of the code has been studied in or applied to federal public health agencies.

By reviewing all sections of the Code of Federal Regulations that pertain to ethical conduct for Executive Branch employees and the published literature derived from congressional oversight of Executive Branch ethics programs, I expect to find information that will be useful in testing the following hypothesis: ***The public health code of ethics is compatible with and distinct from the standards for ethical behavior legislated for Executive Branch employees, and therefore, could be implemented to provide supplementary guidance to public health professionals employed in the PHS agencies.***

In order to address the key question, the approach to the literature review is two-fold. First, the review will identify all relevant legislation that pertains to standards for ethical behavior for the federal public health workforce. Included in the scope of the search are all sections of the Code of Federal Regulations that involve both Executive Branch employees and ethics or standards of conduct. Second, the review will collect and analyze the published reports on congressional oversight of the Executive Branch ethics programs. To accomplish this, the review will collect all relevant publications from the research and investigative arms of Congress: the Government Accountability Office (GAO) and the Congressional Research Service (CRS). These two Legislative Branch agencies conduct policy research and oversight functions for committees and members of Congress. The scope of the search includes all published GAO products (reports, correspondence, and testimony) and all publicly available CRS reports that are related to ethics, ethical behavior, ethics training, ethical standards, Office of Government Ethics, ethics programs, public health service ethics, codes of ethics, and ethical standards. As a result of the review, I expect to have collected all relevant Federal legislation related to the legislated

standards for ethical behavior for Executive Branch employees as well as all congressionally-commissioned and published reports and evaluations of Executive Branch ethics programs.

Search Terms and Criteria

Included in the search are legislation and congressional oversight publications involving two general constructs that are key to my hypothesis: *ethical standards* and *U.S. Public Health Service employees*. The search is designed to capture:

- All relevant legislation governing ethical conduct of Executive Branch employees (and therefore all PHS employees),
- All published GAO and CRS literature, investigations, testimonies and studies on how PHS agencies implement and enforce the legislated code of ethics, and
- All relevant publications on the public health code of ethics in a search of the PubMed and Cumulative Index to Nursing and Allied Health databases.

In order to find the relevant legislation, the review included a search of the Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. Part 2635) for all sections and supplemental standards pertaining to the agencies within the scope of this study

and excluded related authorities and supplemental standards which do not pertain to these agencies. In order to find all relevant, published GAO and CRS literature, I have used search terms including ethics, ethical behavior, ethics training, codes of ethics, ethical standards, and other related terms (see Table 1).

Table 1: Summary of Search Strategy

Resource	Search Terms	Inclusion/ Exclusion Criteria
5 C.F.R. Part 2635 - Standards of Ethical Conduct for Employees of the Executive Branch	N/A: I performed a manual search of the sections of the regulation pertaining to PHS employees including the *Agency Supplemental Standards of Conduct*	**Include:** general provisions, sections pertaining to specifics of standards of conduct for all Executive Branch employees, and supplemental standards of conduct for Public Health Service agencies **Exclude:** related statutory authorities and supplemental standards of conduct for Executive Branch agencies outside of the Public Health Service
Cumulative Index to Nursing and Allied Health	• public health code of ethics • public health ethics	**Include:** articles addressing public health ethics from an organizational or field perspective **Exclude:** articles written in other than English, articles with narrow focus on ethics pertaining to specific disease or condition
PubMed	• public health code of ethics • public health ethics	**Include:** articles addressing public health ethics from an organizational or field perspective **Exclude:** articles written in other than English, articles with narrow focus on ethics pertaining to specific disease or condition
GAO Publications Database	• Ethical behavior • Ethics training • Ethics/Ethical standards • Office of Government Ethics • Ethics programs • Ethics	**Include:** reports related to U.S. Public Health Service agencies, reports issued after the 2002 enactment of 5 C.F.R. Part 2635 *Standards of Ethical Conduct for Employees of the Executive Branch* **Exclude:** reports related to agencies outside the Executive Branch, reports issued prior to enactment of *Standards*
Open CRS Network Database[a]	• public health service, ethics • codes of ethics • ethical standards • ethics	**Include:** reports related to U.S. Public Health Service agencies, reports issued after the 2002 enactment of 5 C.F.R. Part 2635 **Exclude:** reports related to agencies outside the Executive Branch, reports issued prior to enactment of *Standards*

[a] Open CRS Network is a repository for reports and policy briefs published by the CRS.

Since the focus of the review is on Executive Branch experience under the current mandated standards for ethical behavior, the review includes only the literature published after the

standards were codified in October 2002. Table 1 provides a summary of the search terms, inclusion criteria, and exclusion criteria used in this review.

Results

The search included the key components of relevant federal legislation and congressionally-commissioned and published literature on PHS ethics programs and yielded 52 relevant items including 16 sections of the *Standards of Ethical Conduct for Employees of the Executive Branch*, two GAO products, one CRS product, and 33 other items on public health ethics. Table 2 provides a summary of the number of search results with a narrative description of results by resource.

Table 2: Summary of Search Results

Resource	Terms	Total Search Results	Inclusion/ Exclusion Criteria	Relevant Search Results
5 C.F.R. Part 2635 - Standards of Ethical Conduct for Employees of the Executive Branch	N/A: I performed a manual search of the sections of the regulation pertaining to PHS employees including the *Agency Supplemental Standards of Conduct*	44	**Include:** general provisions, sections pertaining to specifics of standards of conduct for all Executive Branch employees, and supplemental standards of conduct for Public Health Service agencies **Exclude:** unrelated statutory authorities, and supplemental standards of conduct for Executive Branch agencies outside of the PHS	16
Cumulative Index to Nursing and Allied Health	• Public Health Code of Ethics • Public health ethics	19	**Include:** articles addressing public health ethics from an organizational or field perspective **Exclude:** articles written in other than English, articles with narrow focus on ethics pertaining to specific disease or condition	8
	• Public Health Code of Ethics • Public health		**Include:** articles addressing public health ethics from an organizational or field perspective	

PubMed	ethics	95	**Exclude:** articles written in other than English, articles with narrow focus on ethics pertaining to specific disease or condition	25
GAO Publications Database	• Ethical behavior or conduct • Ethics training • Ethics/Ethical standards • Office of Government Ethics • Ethics programs • Ethics	2 1 1 8 1 5	**Include:** reports related to PHS agencies, reports issued after the 2002 enactment of 5 C.F.R. Part 2635 *Standards of Ethical Conduct for Employees of the Executive Branch* **Exclude:** reports related to agencies outside the PHS, reports issued prior to enactment of *Standards*	2
Open CRS Network Database	• public health service ethics • codes of ethics • ethical standards • ethics	1 0 1 6	**Include:** reports related to U.S. Public Health Service agencies, reports issued after the 2002 enactment of *Standards* **Exclude:** reports related to agencies outside the PHS, reports issued prior to enactment of *Standards*	1

Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. Part 2635)

The search revealed 16 sections of the *Standards* that pertain to ethical conduct for Executive Branch employees. These sections outlined specific rules and guidance on issues such as accepting gifts from outside sources, exchanging gifts among employees, conflicting financial interests, impartiality in performing official duties, seeking outside employment, misuse of position, and outside activities. The relevant sections offer detailed guidance for employees about what constitutes ethical and appropriate behavior.

GAO Reports

The review included two reports issued since 2002—when the *Standards of Ethical Conduct for Employees of the Executive Branch* were codified—that addressed Public Health Service agency ethics programs. One report studied the NIH policies on recusal from work that may affect a

personal interest (U.S. Government Accountability Office, April 30, 2007). The report found

that the agency had not established clear policies on recusal for senior executives and culminated

in a recommendation that the NIH Director address inconsistencies in the policy and

expeditiously issue a clarified policy. In addition, the background section of the report provided

details regarding NIH's overall ethics training and policies. A second report studied conflicts of

interest among Food and Drug Administration[3] advisory committee members, specifically, their

financial disclosures with regard to interest that may be related to or impacted by outcomes of

Advisory Committee deliberations and recommendations (U.S. Government Accountability

Office, September 30, 2008). This report also provided general description and information on

the agency's implementation of ethics policies and programs.

CRS Report

The review included one report issued since 2002 that addressed Public Health Service agency

ethics programs. The report entitled *The National Institutes of Health: Organization, Funding,*

and Congressional Issues, studied the NIH's ethics and accountability programs and the

agency's efforts to ensure the public's trust (Congressional Research Service, 2008). The report

cited oversight of ethics regulations for the agency and its program to grant the public access to

NIH funded research as issues of particular importance to members of Congress. The report

tracked the progress of implementing several provisions within the NIH Reform Act of 2006 and

covers several areas of Congressional oversight of the agency, including activities aimed at

maintaining trust and transparency.[4]

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[3] The Food and Drug Administration is an agency within the Department of Health and Human Services' U.S. Public Health Service.
[4] P.L. 109-482, December 2006.

PubMed and CINHAL Searches

The literature discovered in searches of the PubMed and CINHAL databases addressing the

public health code of ethics for the most part falls into two categories: 1) articles in which the

author applies an ethical framework to a particular disease or condition (Melnick, Kaplowitz,

Lopez, & Murphy, 2005; Miller, Robert, & Hayeems, 2009; Thomas, Irwin, Zuiker, & Millikan,

2005a; Thomas, Dasgupta, & Martinot, 2007) and 2) articles in which the development of a

public health ethical framework or its applicability in public health education or training is

discussed (Ruger, 2008a; Ruger, 2008b; Stadtländer & Dickens, 2005; Thomas, 2003). The literature

reviewed from these searches revealed no substantive discussion of the utility, adoption, or use

of the code of ethics in federal agencies.

Findings

The review of the literature yielded information that was necessary to address the question: *Is

the public health field's movement to establish a public health code of ethics compatible with

and distinct from the mandated standards of ethical behavior in place for employees within the

U.S. Public Health Service?* In addition, the review provided insights into whether and to what

extent the use of the code of ethics has been studied in the federal workforce.

**Finding #1: The Public Health Code of Ethics is Compatible with the Legislated Standards
of Ethical Behavior in Place for Employees within the U.S. Public Health Service**

None of the elements addressed in the public health code of ethics is in conflict with the

legislated standards in place for employees within the U.S. Public Health Service. A review of 14

sections of the *Standards of Ethical Conduct for Employees of the Executive Branch* and the two

relevant supplemental standards pertaining to PHS agencies and employees revealed that specific items addressed— such as financial conflicts of interest, outside employment, ethics training, and misuse of position— do not conflict with the general guidance set forth in the public health code of ethics. Further, some of the concepts found in the public health code of ethics reinforce sections of the regulations, indicating that they are, in fact, compatible. For example, the twelfth principle in the code of ethics focuses on the importance of public health institutions and their employees building the public's trust and the institution's effectiveness(Public Health Leadership Society, 2002). This tenet is central to the standards mandated for Executive Branch employees. In fact, the first line of the first section of the regulation states, "Public service is a public trust"(5 C.F.R., 2002; 5 C.F.R., 2002). Another principle in the public health code of ethics stresses the need to maintain confidentiality of information to protect the privacy of individuals. This reinforces the mandate in the *Standards* that states that "employees shall not allow improper use of non-public information"(5 C.F.R., 2002). The two documents share some overlapping themes without contradicting each other, indicating their compatibility. In general, the standards mandated for PHS employees are compatible with and are reinforced by the principles advocated in the public health code of ethics.

Finding #2: The Public Health Code of Ethics is Distinct from the Legislated Standards of Ethical Behavior in Place for Employees within the U.S. Public Health Service

The public health code of ethics is distinct from the *Standards of Ethical Conduct for Employees of the Executive Branch* in that they have separate areas of focus. The code of ethics is aspirational and provides broad guidance about the practice of public health aimed primarily at institutions, while the *Standards* are proscriptive and focus on the behavior of individual employees, giving guidance for specific sets of circumstances. A review of the 14 sections of the

Standards of Ethical Conduct for Employees of the Executive Branch and the two relevant

supplemental standards pertaining to PHS agencies and employees revealed that the legislated

standards are focused on rules regarding several specific circumstances— such as giving and

receiving gifts and use of government property. The oversight literature from GAO and CRS

provides further evidence that the focus of the *Standards* is distinct from the broad concepts

outlined in the code of ethics. In one GAO report, the agency recommends that NIH clarify its

policy on employee recusals from work that will affect a personal interest(U.S. Government

Accountability Office, April 30, 2007). While this concept has some element of preserving the

public's trust, its focus on a policy for employees to evaluate an individual relationship to a

project or aspect of work is distinct from the code of ethics' focus on agency or institution-wide

philosophy of involving community to build public trust. Given their separate missions—to

provide broad guidance to institutions in the case of the code of ethics and the establishment of a

code of conduct that prescribes specific behaviors in the case of the *Standards*—the two

documents are distinct and serve different, yet complimentary purposes.

**Finding #3: There has been very little study of the use and applicability of the public health
code of ethics in federal agencies.**

The literature review reveals that there has been very little study of the use and applicability of

the public health code of ethics in federal agencies. The literature addressing the public health

code of ethics typically focuses on 1) the application of an ethical framework to a particular

disease or condition or 2) the development of a public health ethical framework or its

applicability in public health education or training. The literature review revealed little

discussion of the examination or use of the code of ethics in any of the federal agencies.

Discussion

The literature on the use of the public health code of ethics discovered in this review generally

falls into two categories: 1) articles in which the author applies an ethical framework to the

management of a particular disease or condition or studies how others use ethical guidelines to

do so and 2) articles in which the development of a public health ethical framework or its

applicability in public health education or training is discussed. Examples of the first category

include a study by Baum, et.al. in which public health workers in Michigan identified broad

categories of ethical challenges and revealed that few used formal ethical guidelines or

frameworks in their decision-making(Baum, Gollust, Goold, & Jacobson, 2009). Other examples

include work by Thomas which considers how the public health code of ethics might reveal

important considerations in the use of genomic technologies(Thomas, Irwin, Zuiker, & Millikan,

2005b) as well as his analysis of federal and state pandemic influenza plans which for the most

part lacked guidance for ethical decision-making in the event of an outbreak(Thomas et al.,

2007). In addition, Brody, et.al. discuss several frameworks—clinical expert-driven, activist,

and the community-based participatory research model— that can be applied when making

ethical decisions about studying biological samples and reporting results of individual exposure

to pollutants(Brody et al., 2007). There were several illustrations of the second category of

articles describing how ethics is taught to students of public health and how those in the field are

trained and supported (or should be) in their ethical decision-making. MacQueen, et.al. makes

an argument for greater oversight of public health ethics and for recognition of public health

ethics as a distinct field which draws from several disciplines including bioethics, law, and

political philosophy(MacQueen & Buehler, 2004). Several of the articles highlight the important

distinctions between medical and public health ethics—primarily that the medical and bioethical

perspective involves the interaction between individuals (doctor/patient, researcher/subject), while the public health model focuses on the interactions between institutions and the populations they serve (public health programs/communities). Bayer and Fairchild describe a "deep divide" between the commitments and values of bioethics and public health practice by way of advocating that public health should have its own, unique ethical framework, separate from the bioethical model(Bayer & Fairchild). The literature review revealed no substantive discussion of the use of the code of ethics in federal agencies. One exception is an article describing the CDC's efforts to strengthen the agency's leadership in public health ethics(July/August 2008). According to Barrett, the effort is centered on building an administrative infrastructure for ethics within the agency and for applying public health ethics to particular program concerns within the agency.

Strengths and Limitations of the Literature

After determining that the public health code of ethics and the *Standards of Ethical Conduct for Employees of the Executive Branch* are complimentary and distinct, it is useful to examine the quality of literature on which these conclusions are based. There are several strengths and weaknesses that should be taken into account when considering these findings.

An advantage of using GAO and CRS published literature to learn about the implementation and effectiveness of Executive Branch ethics programs is that those Legislative Branch agencies have greater access to Executive Branch agency information than would a researcher relying on publicly available data or requests for data made through the Freedom of Information Act.[5] In addition, the GAO has subpoena power to obtain relevant information from agencies it studies in

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[5] The Freedom of Information Act allows for the release of previously unpublished information controlled by the U.S. government and ensures public access to some government records.

order to fulfill a congressional request. The result of this enhanced access, is that the studies can include documentation, interviews, and other data from Executive Branch agencies to which researchers outside of GAO and CRS would not have access.

While the increased access to information is a strength of GAO and CRS literature, the nature of how the studies are commissioned presents a critical limitation. With some limited exceptions, the studies conducted by these agencies are in response to congressional requests, often to provide an evidence-base for potential legislation or to inform a particular political agenda. In conducting the studies, GAO and CRS are not always at liberty to pursue other avenues that arise during the research phase of a study or explore related topics that fall outside of a tightly managed scope of study. While the studies are conducted within a system with rigorous controls to ensure non-partisan and balanced research, there is limited freedom to shape the research agenda.[6] Another limitation of this review is incomplete access to all CRS products. Because CRS publications are not routinely released to the public by the agency or by the members of Congress who requested them, it is not possible to review the universe of CRS publications on a given topic. A requester may elect to publicize a report, but is not obligated to do so. This review included a search of the Open CRS Network which was established to collect and make available any CRS publications voluntarily released by congressional requesters. There is no repository for all CRS publications, so the review included a search of only those that have been released to the public. Finally, a lack of published literature on how the public health code of ethics is used in federal agencies may not adequately capture current practice. It is possible— and perhaps likely—that internal discussions and policy formulation regarding federal ethics programs would not result in peer reviewed, published literature, but rather would be

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[6] In the case of GAO, a small portion of the work conducted is identified by the agency as opposed to a congressional requester.

documented in internal agency materials that may or may not be available to the public.

Gaps in the Literature and Considerations for Future Research

None of the products reviewed from GAO and CRS directly addressed the relationship between professional codes of ethics—such as the one for public health or for medical personnel—and mandated codes or standards of ethics. The articles selected for this review contained research findings and discussion of federal ethics issues and programs specific to individual agencies and did not address Executive Branch workforce in general. These gaps in the literature revealed some areas for future study that I will consider for the dissertation. First, the lack of published literature on how the public health code of ethics is used in federal agencies indicates that the strategy of conducting key informant interviews and reviewing available documentation about agency ethics programs may be more effective means of capturing current practice. Another area for future study is consideration of lessons that might be learned from a comparison of the interplay between professional codes of ethics and mandated ethical standards for other professions that are similarly rooted in the federal government such as medicine.

CHAPTER 3: METHODS

The research design and analysis undertaken for this study were intended to address the study's

key research questions:

- In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and NIH, the two largest federal public health agencies?

- To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?

- If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?

By combining methods for data collection—document review and key informant interviews—

the information gathered was triangulated. This allowed for information gathered by employing

one method to be corroborated and verified by information collected by the other method.

Section I: Data Collection

To learn about the CDC's and NIH's current practices, how they align with the public health

code of ethics, and how changes to the ethics programs could be implemented, I employed a

sequential information-gathering strategy involving document review and key informant

interviews (see Figure 4). First, I conducted a search for publicly available information for the

CDC and NIH regarding the current programs, policies, guidelines, and procedures for ethically

conducting their public health missions. I compared this information with the 12 principles in

the public health code of ethics in order to identify particular areas where gaps between the

code's principles and the agencies' programs may exist. I used that analysis to inform and refine

a set of questions for interviews with agency officials.

Figure 4: Concept Model for Data Gathering
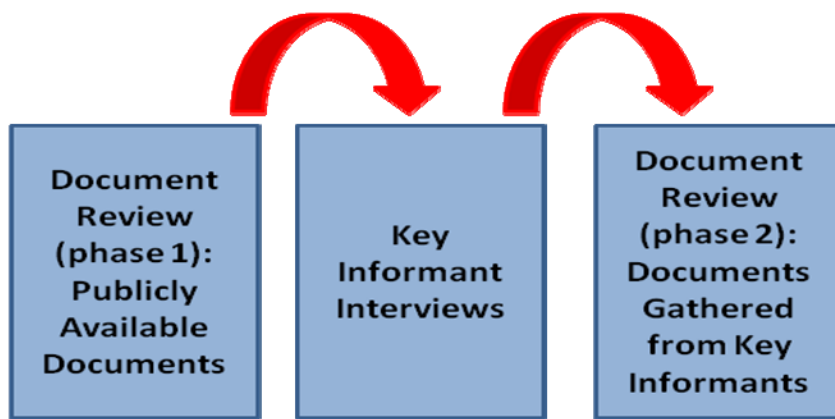
Next, I conducted key informant interviews with ethics personnel from CDC and NIH. The

interviews were used to verify and clarify the information from the first phase of document

review and to ascertain study participants' opinions of the code of ethics and whether they think

it includes principles that could address gaps in and be added to the current agency ethics

programs and policies. I also explored what the barriers are to adopting the principles of the

code of ethics in each agency. One of my goals for the key informant interviews and document

review was to understand how a change to each agency's ethics program would happen—who

the decision-makers are, what the steps would be for change, what the barriers are, etc. An

additional goal was to determine whether there are principles within the code of ethics that may

not be currently covered in the agencies' ethics programs, and if so, whether officials believe

there would be a benefit to addressing them. Finally, after analyzing information from both

methods of data collection, I determined what a reasonable strategy would be for incorporating any relevant changes into the fabric of the agency.

Because decision-making procedures between the two agencies in this study are rarely formalized in public documents, interviews were a vital research tool to learn the agencies' processes for making changes to their ethics policies. As appropriate, I requested documentation to support participants' responses. The final stage of data gathering was a second phase of document review wherein I collected documentary support from interview participants during the course of the interviews and reviewed and analyzed that information to further verify the information gained from the first two stages of data collection. While study participants did not provide sensitive agency materials, in the course of the interviews, they did identify and offer documents or support materials that were useful for this study, and were not available through a search of agency web sites. This set of documents was predictably small, but did yield some significant insight into the CDC's process for educating its workforce about the code of ethics. For example, a CDC official shared an internal survey used to determine familiarity with and attitude about the public health code of ethics that was currently being fielded with the agency's employees. This document was not posted on the agency web site and was not otherwise available to the public.

Study Participants and Recruitment

Study participants included individuals with professional responsibility for developing, conducting training about, and overseeing ethics programs and policies at the two largest federal public health agencies—CDC and NIH. In addition, the study included participants who were instrumental in developing the public health code of ethics, knowledgeable about its history, or

actively working to disseminate the code. Fourteen potential participants were identified through

initial document review and through personal contacts and were invited to serve as key

informants for the study, including ethics officials from CDC, NIH, and HHS and individuals

who participated in the development of the code of ethics. Potential participants were selected

for their knowledge of ethics programs and internal process for adapting those programs at CDC

or NIH. In addition, participants were selected for their direct experience in the development

and/or dissemination of the code.

Table 3: Invited Study Participants, Affiliations, and Interview Status

Invited Participant	Affiliation	Interview Status
Dr. Drue Barrett CAPT, U.S. Public Health Service Public Health Ethics Coordinator Office of the Chief Science Officer	CDC	Completed
Ruth Gaare Bernheim, J.D. CDC Public Health Ethics Committee Co-Chair, PHLS Public Health Ethics Committee	CDC / PHLS	Completed
Vence Bonham, J.D. Associate Investigator and Senior Advisor to the Director on Societal Implications of Genomics Branch Chief, Education and Community Involvement National Human Genome Research Institute	NIH	Completed
Terry Brandenburg, MPH, CPH Former Board member Public Health Leadership Society	PHLS	Completed
Dr. Christine Grady Acting Chief, Department of Bioethics Head, Section on Human Subjects Research	NIH	Completed
Holli Beckerman Jaffe, J.D. Senior Policy Officer, NIH Ethics Office Deputy Ethics Counselor, Office of the Director	NIH	Completed
Dr. Lisa M. Lee Assistant Science Officer Former Ethics Coordinator	CDC	Completed
Dr. Alan Melnick Co-Chair, PHLS Public Health Ethics Committee	PHLS	Completed
Gretchen H. Weaver, J.D. Senior NIH Ethics Counsel Department of Health and Human Services, Ethics Division	NIH/ HHS	Completed
Representative	CDC/PHLS	Scheduled, but not completed
Four Representatives	PHLS	No response

Ten invitees agreed to be interviewed for this study with nine completing an interview. Of the fourteen who were invited, one respondent agreed to be interviewed, but did not complete an interview, and four invitees—all from the Public Health Leadership Society (PHLS)—did not respond to the invitation. Table 3 provides a list of key informants and others invited to participate, their affiliation as it pertains to the topics addressed in the study, and the status of their participation.

Interviews were conducted by telephone between March 3, 2010 and April 15, 2010 and were recorded with the permission of the participants. Procedures and written information provided to the potential participants were approved by the University of North Carolina Institutional Review Board (IRB). To recruit key informants, I sent an e-mail explaining the research study and asking whether selected individuals would be willing to participate in an interview to discuss the public health code of ethics and their respective agency's ethics programs or their role in the development and dissemination of the code. For those willing to participate, I scheduled an interview and sent a fact sheet (see Appendix A) and the public health code of ethics in advance of the discussion. The procedure for participants was as follows:

- Read the fact sheet to determine interest in participating in the study
- Contact the researcher with any questions or concerns regarding participation
- Schedule a time to participate in a 30-45 minute telephone interview[7]
- Read the 12 principles of the code of ethics entitled *Principles of the Ethical Practice of Public Health* before the interview and consider whether or how it aligns with the participant's agency mission
- Participate in a 30-45 minute interview

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[7] This time was adjusted from the original fact sheet request for a 45-60 minute interview.

- Address follow up questions or clarifications if needed after the interview

Individuals were informed that they may benefit from participation in this study by discovering ways the public health code of ethics could enhance the current ethics programs and policies in place within the agency where the participant is employed. The interviews with key informants (federal agency officials and others), were designed to elicit and clarify details regarding ethics programs, policies, and practices within their agencies or organizations. These programs are, by their very nature, public, and so participation was unlikely to pose a risk. However, any potential risk was mitigated by allowing participants to opt for confidentiality of information, in which case I would not identify the name, position, or any other element that may allow the reader to ascertain the identity of individual participants in the report of study results. All participants agreed to have their names used to affirm their participation; however, several participants asked not to have quotations attributed to them. As a result, all direct quotations from key informants included in the results of this study are characterized to describe the speakers' affiliation, but not directly attributed to participants by name.

Interview Format and Privacy of Information

When participants agreed to be interviewed for the study, I made appointments in advance with the key informants, allowing them the opportunity to schedule the interview at a time convenient for them to participate in a 30-45 minute discussion by telephone. The interviews proceeded according to the interview protocol approved by the IRB with questions that moved from general to specific and follow the following question scheme:

- Opening: to ease the participant into discussion with a question about her/his role in the agency's ethics program;
- Introductory: a broad question to check familiarity with the public health code of ethics;
- Key Questions: the questions that are the crux of the interview and are the most important since they directly address the study's key research questions; and
- Ending: a request to prioritize earlier responses, clarify any information from the interview, and an invitation to indicate any other areas of inquiry or agency contacts that may be relevant to the study.

The framework used for sequencing, phrasing, and delivery of interview questions is consistent with best practices for qualitative research and is modeled on the concepts for developing qualitative questioning routes for key informant and focus group interviews (Krueger, Richard A. and Casey, Mary Anne, 2000; National Cancer Institute, 2002). The interviews concluded with a request for permission to contact the participant in the future if additional questions or need for clarification arose. During the interviews, participants were asked whether there was documentation they could share to support certain responses. This yield a small, but insightful collection of documents that are not posted publicly, but are not classified or sensitive and could therefore be made available for this study.

Prior to beginning the interview questions, I asked the interviewees for permission to audio record the discussion for later transcription. Participants had received a full written description of the study prior to the key informant interviews and had an opportunity to ask questions and/or express concerns via e-mail or telephone prior to scheduling the initial interview as well as at the outset of the interview appointment. In addition, I obtained the participants' verbal consent to participate at the time of the interview, prior to any data collection.

In general, the study discusses interview results in the aggregate, attributing statements to "officials at NIH" or "CDC ethics staff." In some cases, in order to demonstrate the credibility of a statement or to provide evidence that a statement was given from a person with the

appropriate experience, training, or position to speak with authority on a topic, I attributed

statements to a particular individual by describing the participant's position when the participant

granted permission. I asked research participants for permission to attribute statements and

information shared in the interview, resulting in some granting permission and others asking to

review specific statements prior to attribution. Other procedures for assurance of privacy

included:

- The principal investigator is the only person who has access to information that links individual participants to the responses from their interviews.
- Participants were asked for permission before being identified in the study.
- Records of the interview are stored electronically in protected files.
- At the time of the interview, participants were asked for permission to record the interview for transcription. All interviews were recorded, and a written transcript was made and stored securely.
- Any hardcopy information linked to an individual's responses to interview questions were stored in a secure location.

There were no monetary or explicit non-monetary incentives to participate in this study, other

than my offer to provide a copy of the completed work after committee approval. In addition,

there were no costs to be borne by subjects, other than their time.

Special considerations

Disclosure of GAO employment

The agency where I am employed—the GAO— serves an oversight function for the Executive

Branch, including the two agencies within the scope of this study. I disclosed my professional

affiliation to each participant and assured those invited to be interviewed that any data collected

for this project would not be shared with GAO for any active engagement. The disclosure did

not result in any interviewees changing their minds about participating in the study nor did it

appear to have an impact on the candor with which participants spoke about their agency's ethics programs and activities.

Affirmation of non-advocacy stance

I made clear to research participants that I am not involved in the writing or dissemination of the public health code of ethics and that I do not have a stake in its acceptance or failure. The study explores how the public health code of ethics could be used to fill gaps in ethics programs at NIH and CDC and is not designed to advocate for its adoption in the federal system. However, the participants were informed that study findings may lead to recommendations for the code as a whole or for particular principles of the code to be adopted or addressed by the agencies if gaps are found.

Document Review

Given that the document review was performed to ascertain the extent to which the CDC and NIH have programs, policies, and practices in place to address the 12 principles in the code, the code itself served as the framework for the search for documents on the web sites of each agency. The sources for the search for documents and other publicly available information on the agencies' ethics activities included the CDC and NIH web sites and Google. The search terms and system for capturing documents for this study are summarized in Table 4. In addition to a systematic search using the terms noted in Table 4, the search for documents and other information included reading widely on both the CDC and NIH web sites and from the material found as a result of Google searches.

The goal of the document review was not to catalog all programs that relate to the code's principles, but rather to indicate whether any agency programs or activities could be linked to each principle. In some cases, there were numerous programs that pertained to a given principle, in which case only a few were selected for inclusion in the study findings. In this case those with agency-wide focus were given preference over those carried out at the institute or division level. For example, the first portion of principle 6 reads, "Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs." When searching for examples of programs that address this concept, numerous public health and education materials and campaigns surfaced such as those translating research into messages regarding heart health, nutrition, diabetes treatment and prevention, etc. Rather than list the many examples that exist at the institute level, the study focuses on the policies that exist agency-wide to address this principle.

Table 4: Search Terms and Sources Used for Collecting Documents on CDC and NIH Ethics Activities

Public Health Code of Ethics Principles[a]	Search terms used on CDC and NIH web sites and Google[b]
1) Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes	• "causes of disease" • prevention • "adverse health outcomes"
2) Public health should achieve community health in a way that respects the rights of individuals in the community	• "community health" • "rights of individuals"; "individual rights"
3) Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members	• "community input" • input; feedback
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	• "minority health"; minority • "health disparities"; disparities
5) Public health should seek the information needed to implement effective policies and programs that protect and promote health	• "health promotion"
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	• "community consent"; consent
7) Public health institutions should act in a timely manner on	• communication

the information they have within the resources and the mandate given to them by the public	• results
8) Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community	• "minority health"; minority • "health disparities"; disparities
9) Public health programs and policies should be implemented in a manner that most enhances the physical and social environment	• "environmental health" • 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	• "human rights" • "human subjects" • consent
11) Public health institutions should ensure the professional competence of their employees	• "staff education" • development • training
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.	• "public trust" • partnership

[a] *Principles of the Ethical Practice of Public Health*, Public Health Leadership Institute, 2002.
[b] Search terms were the same for the agency web sites and for Google except that for Google searches, terms were preceded by the agency acronym (CDC or NIH).

Section II: Data Analysis

Qualitative primary data was collected for this study from key informant interviews, the analysis of which paralleled the key research questions.   All recorded interviews were transcribed and printed for analysis. Responses were reviewed and manually coded by the major themes covered in the interview protocol and key research questions including: current practices within CDC and NIH that address the principles within the code, familiarity with the code of ethics, deliberation within the CDC and NIH regarding adoption of the code, barriers to adopting the code, and the processes within CDC and NIH for making changes to the ethics programs when gaps are identified. Table 5 summarizes these themes as well as those derived from the document review and relates them to the key research questions.

Table 5: Summary of Key Themes Analyzed and Their Relationships to Key Research Questions

Key Themes Analyzed	Addressed by Interviews	Addressed by Doc Reviews	Key Research Question Addressed
CDC and NIH ethics practices/ programs	X	X	Question 1: current practices that address the code
Familiarity with code	X	X	Question 2: adoption of code considered
Whether adoption of code was discussed within agencies	X	n/a	Question 2: adoption of code considered
Barriers to adopting the code	X	n/a	Question 3: how barriers can be addressed/changes made
Agency processes for changing ethics programs	X	n/a	Question 3: how barriers can be addressed/changes made

Secondary data was collected in the form of two phases of document review and analysis: phase one (prior to key informant interviews) based upon publicly available documents regarding the agencies' ethics programs and policies and phase two based upon documents requested from or offered by key informants during the course of interviews. The analysis for this study flowed from the three data collection stages and was performed concurrently with data collection (see Figure 5).

Figure 5: Concept Model for Data Analysis
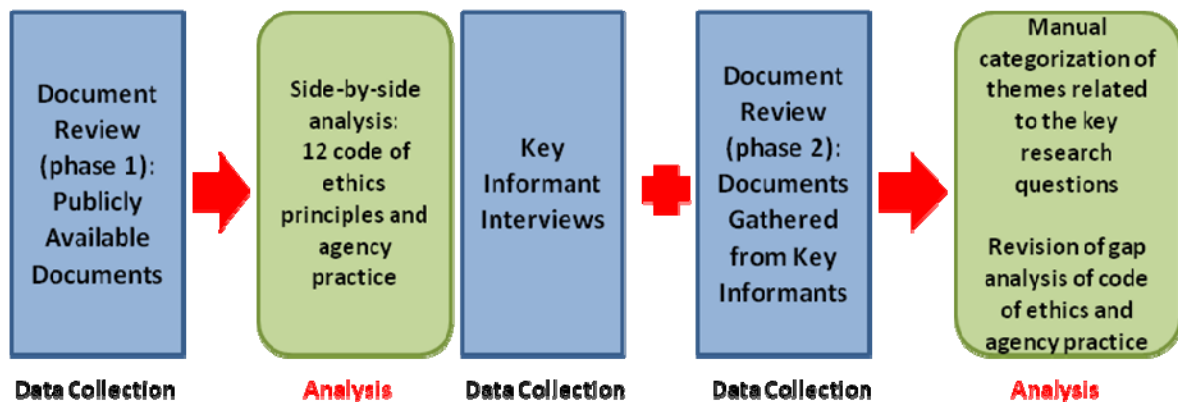
The information from the first phase of document review was used to perform side-by-side and gap analyses to: 1) determine what the current ethics practices are in each agency and compare them side-by-side with the twelve principles of the code of ethics, and 2) identify any gaps, or principles of the code of ethics not currently addressed by the agencies. These analyses helped to inform the interviews with key informants. Through the course of the interviews, participants offered or I requested documentation to support participants' responses to interview questions and to further illustrate points they raised in the discussion. Interviews and the second phase of document review informed revisions to the gap analysis of the code of ethics and current agency practices. This analysis led to categorization by themes expressed in the research questions into findings and subfindings, a discussion of the findings, a presentation of conclusions, and a plan for change.

CHAPTER 4: RESULTS

OUTLINE

Introduction

Section I: Key Informant Interview Findings

❖ *Description of Sources*

❖ *Key Findings*

➢ *Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?*
   ▪ **Key finding 1.1: Information collected from key informants affirmed that CDC and NIH have ethics programs and activities that address all or most of the 12 principles of the public health code of ethics**
      • **Subfinding 1.1.a: CDC officials described programs and activities that address all of the principles in the code of ethics**
      • **Subfinding 1.1.b: NIH officials described programs and activities that address ten of the principles in the code of ethics**

➢ *Key Question 2: To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?*
   ▪ **Key finding 2.1: Familiarity with the public health code of ethics varied dramatically between agencies: All CDC officials and associates interviewed for this study were familiar with the public health code of ethics, and none of the NIH officials had seen or heard of the code before being interviewed for this study**
   ▪ **Key finding 2.2: The CDC has considered formally adopting the code and has declined to do so**
   ▪ **Key finding 2.3: Officials at both agencies identified potential barriers to adopting the code, leading to mixed opinions about the benefit of doing so**

- **Subfinding 2.3.a: CDC and NIH officials identified legal obligation and agency authority as barriers to adopting the code**
- **Subfinding 2.3.b: CDC and NIH officials recognized the lack of a clearly articulated rationale for the code as a barrier to its adoption**

➢ *Key Question 3: If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?*
- ▪ **Key Finding 3.1: The CDC and NIH each has a process for considering additions or changes to agency ethics programs which would allow gaps in their programs to be addressed.**

Section II: Document Review Findings

❖ *Description of sources*

❖ *Key Findings*

➢ *Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and Prevention and the NIH, the two largest federal public health agencies?*
- ▪ **Key finding 1.2: There are programs at CDC and NIH that address most of the 12 principles of the public health code of ethics**
  - **Subfinding 1.2.a: CDC documents show that the agency has programs and activities that address most of the principles in the code of ethics**
  - **Subfinding 1.2.b: NIH documents show that the agency has programs and activities that address most of the principles in the code of ethics**
  - **Subfinding 1.2.c: The review of publicly available documents revealed some gaps between agency ethics programs and the public health code of ethics**

The key informant interviews and document review were designed to provide insights into the study's three key questions from different perspectives. The goal of the key informant interviews, was to develop an understanding of each agency's organization, resources, and practices devoted to addressing the principles within the public health code of ethics and to tap into any information not readily available through a search of publicly available information. The objectives of the document review were to provide an agency-level overview of organizational components, programs, and policies that address the principles in the public health code of ethics, to illuminate any potential gaps between the code's principles and the agency's practices, and to determine targeted areas of questioning for key informant interviews with agency officials. The findings of both study components –the key informant interviews and the document review—are summarized along that analytical framework in this chapter.

The three key research questions for this study are:

- Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?

- Key Question 2: To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?

- Key Question 3: If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?

The goal of the key informant interviews was to address the latter two key questions by determining current practices, whether either of the agencies has considered formally adopting the code of ethics, what the barriers are to doing so, and what the process would be for introducing changes to the ethics programs in the two agencies. Additional goals of the key informant interviews were to access information about the agencies' ethics activities and programs not readily available through a search of publicly available documents and to learn about the history of the code from those instrumental in developing and disseminating it. The objectives of the document review were to address the first key question, namely to provide an overview of ethics activities and programs conducted at the CDC and NIH and to determine to what extent they address the 12 principles in the public health code of ethics.

Section I: Key Informant Interview Findings

Description of Sources

Key informants interviewed for this study fall into three categories: officials and others associated with the ethics programs at CDC, ethics officials at NIH, and individuals with knowledge and experience in the development and dissemination of the code of ethics. In some cases an individual fell into more than one category, such as an agency official who was also instrumental in the development of the code. Interviewees and their roles with the agency ethics program or code of ethics development included:

- A CDC public health ethics coordinator and chair of the CDC Public Health Ethics Committee composed of representatives from each of the agency's centers and a variety of other offices and special workgroups. This individual also serves as the designated

federal official for the Ethics Subcommittee of the Advisory Committee to the Director, which is a group of external advisors who provide input to CDC on a broad range of public health ethics issues.

- A CDC official who oversaw public health ethics activity at CDC, specifically the implementation of the activities related to the agency's internal public health ethics program and the external public health ethics advisory committee. This individual is also active in the agency's public health ethics education activities in addition to some work specifically on research and human subjects ethics.

- A university professor who serves as a member of the CDC's external public health ethics advisory committee, serves as co-chair of the Public Health Leadership Society's Ethics Committee, oversees her school's Public Health Program, and has a long history of working on the Code of Ethics from its development to current efforts to disseminate it via speaking engagements and on-line seminars.

- The Acting Chief of the NIH's Department of Bioethics and head of the Section of Human Subjects research. This individual is based in the NIH's Clinical Center and also works in the Intramural Research Program at NIH.

- An NIH intramural investigator and administrator within the Human Genome Institute involved with issues related to ethics, conflicts of interest, and compliance with rules regarding human subjects. This individual's research is related to the translation of new genomic information to the clinical setting and into public health settings. In addition, this individual serves as an adviser to the institute director on societal implications of genomics, including policy matters and how genomics is being used both in a research setting as well as its translation to clinical use as well as the society more generally.

- An NIH attorney who has been working in the area of Federal government ethics for close to two decades. This individual served as an attorney in the General Counsel's Office in the Ethics Division at NIH which coordinates 31 different ethics offices across the NIH campus. This individual now serves as the Senior Policy Officer in the NIH Ethics Office, setting policy and coordinating training for NIH employees and ethics officials.

- The Senior NIH Ethics Counsel, an attorney in the Department of Health and Human Services Office of the General Counsel's Ethics Division who advises those who are coordinating government ethics programs and oversees how the ethics program is being implemented.

- Co-chair of the Ethics Committee for the Public Health Leadership Society who has worked on the development of the code as well as its dissemination through speaking engagements, on-line seminars, and work with local, state, and federal agencies to encourage them to consider the code of ethics in their work.

- A member of the Public Health Leadership Institute Board at the time of the code's development and current Health Commissioner of his county's health department.

Key findings

Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?

Key finding 1.1: Information collected from key informants affirmed that CDC and NIH have ethics programs and activities that address all or most of the 12 elements of the public health code of ethics

The key informants interviewed for this study commented on the extent to which the mission and work of their agencies aligned with the principles that make up the public health code of ethics.

Information from the interviews revealed that both agencies have ethics programs and activities in place that address most or all of the 12 principles found in the code. In addition, there was general agreement among CDC and NIH officials interviewed for this study that the missions of both align well with the code's principles and/or are addressed by current activities within the agencies (see Table 6).

Table 6: Specific Mentions by Key Informants of the 12 Principles from the Public Health Code of Ethics as Having Alignment with Agency Mission or Programs

Principle from Code of Ethics (summarized)	CDC	NIH	Potential gap?
1) address fundamental causes of disease and requirements for health, prevent adverse health outcomes	✓	✓	no
2) achieve community health in a way that respects the rights of individuals in the community	✓	✓	no
3) ensure an opportunity for input from community members	✓	✓	no
4) empowerment of disenfranchised community members	✓	✓	no
5) implement effective policies and programs that protect and promote health	✓	X	Yes for NIH
6) obtain the community's consent for their implementation	✓	✓	no
7) act in a timely manner on the information they have	✓	✓	no
8) incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community	✓	✓	no
9) enhance the physical and social environment	✓	X	Yes for NIH
10) protect the confidentiality of information that can bring harm to an individual or community	✓	✓	no
11) ensure the professional competence of employees	✓	✓	no
12) engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness	✓	✓	no

Note: a check mark indicates that at least one key informant mentioned at least one program or policy specifically addressing the principle. An "X" entry indicates both that no interviewee offered examples of alignment with agency work and at least one key informant expressly noted that the principle falls outside of the agency's mission or the agency does not have policies or programs to address it.

This section will expand on the summary in Table 6 to report findings first from CDC officials, then from NIH officials including their opinions on how well the principles align with their respective agencies' missions and specific programs they mentioned that address the principles.

Subfinding 1.1.a: CDC officials described programs and activities that address all of the principles in the code of ethics

When asked whether any of the principles stand out as concepts that although aligned with the agency's mission, are not addressed by current ethics programs, A CDC official responded that, "I would say they all align with our work." Another said, "I think it's a gestalt of the list of the 12 of them that resonates with us," noting that while there may be some in the agency who would argue that the phrasing of the principles could be tweaked or improved, the concepts represented within them are sound and align with the mission and work at CDC. Officials further noted that there are several programs that relate to specific principles, and others that seem to be more infused into the culture and all the work that CDC does. For example, regarding the fourth principle—"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 for all"— the agency has a program called Racial and Ethnic Approaches to Community Health, or "REACH" within its Chronic Disease Center that aims to empower disenfranchised communities and a program in the Agency for Toxic Substances and Disease Registry (ATSDR) that works with tribal communities that serve as examples of ways this principle is addressed by current programs. More broadly, the official noted that concepts expressed in the first principle—"public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes"—are not captured in a single program, but rather are an integral part of the agency's mission that

permeates all the agency's work saying, "Clearly, everything we do here is about the importance of science underlying decision-making and is in place at all CDC's programs." Similarly, regarding the tenth and eleventh principles—"public health should protect the confidentiality of information…" and "public health institutions should ensure the professional competence of their employees"— the official noted that "There's the emphasis on confidentiality of information for all programs. There's a privacy officer and a confidentiality officer here. And then in terms of professional competence, there's a whole group that just deals with workforce development issues." Other ways the agency addresses the professional competence of its workforce is through several fellowships for developing public health professionals such as the Epidemic Intelligence Service which this official described as "a two-year fellowship for training public health professionals… sort of an on-the-job training" and a fellowship in public health ethics through Tuskegee University.

The extent to which the public health code of ethics aligns with CDC's work is underscored by the fact that there are efforts underway in the agency to disseminate the code and to evaluate its employees' awareness of its principles. Part of the agency's public health ethics activity has been dedicated to workforce education and development in two ways that highlight the code of ethics. First, the ethics office has fielded a first-of-its-kind CDC-wide survey to determine its workforce's awareness about the public health ethics activities at CDC as well as its awareness about public health ethics in general. The survey includes a question specifically about the public health code of ethics. The goals of the survey were to get a sense of how many within the CDC workforce know about the topic of public health ethics and about the code itself. The survey was being fielded at the time the interviews were conducted for this study. CDC officials

expect results to be reported at the APHA conference in November 2010. Preliminary results were not available at the time this study was conducted.

A second effort is the agency's public health ethics online training which was a year in development and includes a section devoted to the public health code of ethics. That section includes a listing of the code's principles, a module on its contents, and a self-assessment with specific questions about the users' knowledge regarding the code's principles. CDC officials said that the training is now available to all CDC employees, contractors, and others, and is part of an effort to disseminate the code and "to really help put these things out in front of folks." The agency also offers other ethics training opportunities to its staff including an annual lecture from an outside speaker who talks about some key issues regarding public health ethics. In addition, the agency offers a quarterly training opportunity for staff wherein the agency collaborates with the Emory University School of Public Health Center for Ethics to bring a guest speaker or trainer to discuss or lead a group discussion of topics in public health ethics.

According to agency officials, in formal and informal ways, the leadership at CDC is using the code of ethics and seeks to raise awareness about it among the public health workforce. One official noted that CDC's ethics leaders try to highlight the code of ethics in the course of their own professional interactions, providing several examples from personal experience:

> "Whenever I do talks, I always bring along a copy of the code of ethics and I refer to it. Often, I will ask CDC staff, how many of you know that there is a code of ethics out there? And actually, in the beginning, not that many people knew but I think more and more, as I do more talks, more people are aware that it exists. Of course, we have links to it on our website. So we are trying to make sure people are aware of it and we refer to it, and we see it as a good documentation of the values in public health and some of these guiding principles. But we're not viewing it as our one and only code of ethics."

Another way this is happening is through a collaboration with colleagues outside of the agency who serve on CDC committees or are otherwise associated with the agency to infuse the code of

ethics into presentations and partnerships for state and local public health workers. Specifically, CDC is working with a member of its Ethics Advisory Committee and others to host a seminar with the goal of identifying ways state health departments can implement the code. In summary, one CDC official noted that regarding public health ethics training for staff and external partners, "there are a variety of things that we offer and that people take advantage of." The key informants from CDC indicated that the principles in the code of ethics are integrated to a high degree into the agency's training and other education offered to the CDC workforce and others in the field of public health, illustrating their point that the principles align strongly with the agency's mission.

Subfinding 1.1.b: NIH officials described programs and activities that address ten of the principles in the code of ethics

The NIH officials interviewed for this study also indicated that the principles within the code generally aligned well with the mission of the agency, but noted some exceptions. One key informant stated that, "I think that individually, many of the principles actually align very well with what we do." However, the official also raised the issue that some of the principles relate specifically to the implementation of public health programs which the official believes does not necessarily align with NIH's mission, stating, "that's not what the NIH is supposed to do— implement programs." The official pointed specifically to the fifth and ninth principles—"public health should seek the information needed to implement effective policies and programs that protect and promote health" and "public health programs and policies should be implemented in a manner that most enhances the physical and social environment" – as principles perhaps not in alignment with the core work at the agency, saying, " I guess both of those speak to implementation in a way that doesn't seem to make sense in terms of how I understand what the

NIH does." These comments point to a key difference between the CDC and NIH in that although there are important public health programs coordinated by the NIH, the NIH's ethics programs are much more focused on biomedical ethics and the protection of human subjects given the agency's mission as a research institute, while the CDC has dedicated resources to and recognizes public health ethics as an important part of its overall ethics program.

Despite this difference, NIH officials affirmed that most of the code's principles are addressed in some way by the agency's ethics activities and programs. Typically, they described the concepts within the code as in alignment with the way NIH does its work, whether defined as "public health" or biomedical research. For example, one NIH ethics official recognized general alignment of NIH's mission with several of the principles stating:

> "I think for the most part, number one is addressing fundamental causes of diseases. That's really what the NIH mission is supposed to be about in terms of its research. The second one is respecting the rights of individuals in the community ... That's certainly what the NIH is about. The third one is about community input and there are lots of ways that the NIH goes about getting community input on a regular basis … The fourth one is about advocating for the empowerment of disenfranchised communities. That's a little less directly what NIH does but certainly there's a large emphasis on research to reduce health disparities… The sixth one is about providing information. NIH has a large role in providing information to the general public about research and health. The seventh one is about acting in a timely manner on the information they have, so certainly, any time there's a research result that the NIH is responsible for in some way, it has a moral responsibility to get that out to the public and, I think, takes that responsibility very seriously. Incorporating a variety of approaches that anticipate and respect diverse values, beliefs and cultures in the community -- I do think that the way we go about engaging communities and the way we go about deciding research priorities and the way we go about conducting research all sort of takes that into account. Confidentiality - that's a big thing that everybody pays attention to. Professional competence - that's again something that as an institution, I think, we do pretty well. And how we engage in collaboration and affiliation, these are things that the NIH does pay attention to."

Another NIH official highlighted the agency's work to ensure that "all communities have a voice," underscoring that public health has a particular interest in underserved or marginalized communities—the concept addressed by the code's fourth principle. Coupling that idea with the twelfth principle—"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"—this and other officials at NIH recognized the importance of building and maintaining the public's trust in the way the agency uses the taxpayers' money to carry out its mission. Specifically, this official sees the role of being good stewards of the public's money and service to the underserved as intertwined and relevant to the agency's work noting, "How we use the $30 billion plus that NIH receives is actually impacting communities, is not just impacting technology, but [serving] those that may be underserved or marginalized. So I think that clearly, the statements [principles] here are relevant and have importance for the work of NIH." Officials emphasized the agency's efforts to assess and minimize conflict of interest among its staff and grantees as an example of how it addresses the twelfth principle in the code. Specifically, one key informant noted,

> "I think we run our standard of conduct rules so that the public health institution, the NIH, and their employees engage in all of their official duties in ways that build the public's trust, not just collaborations and affiliations. And that it maintains the institution's effectiveness in the sense that nobody would question our results, that everybody who reads the results of NIH research would say, 'That's always done to the public's advantage,' that the public's health is always put first and foremost in all the research that we're conducting. So I do think we administer our programs very much so consistent with [principle] number 12."

This official further noted that leaders within the agency frequently talk about the ways in which they can avoid putting the public's trust in NIH at risk and consider a rigorous enforcement of the standards for ethical conduct, including conflict of interest guidelines as an important tool in doing so. For example, one official said that a "reasonable person could lose trust in the NIH programs if he or she thinks that the programs are being administered in a way that the public's health is not first and foremost." Finally, officials mentioned the agency's Council of Public Representatives (COPR) as a program that addresses the third principle—"public health policies, programs, and priorities should be developed and evaluated through processes that ensure an

opportunity for input from community members." The COPR is comprised of members of the public and advocates for people living with diseases and conditions studied by NIH and serves in an advisory role to the NIH Director, ensuring that there is community input into the agencies program and funding decisions. In addition, one interviewee cited the requirement that federal agencies provide public notice and opportunity for comment for certain program decisions as an additional means of addressing this principle.

In general, officials from both agencies indicated that the code's principles align closely with the agencies' missions and work. Exceptions to this were from NIH officials who did not readily identify programs or activities to address or mission alignment with two of the principles. Specifically, officials did not offer examples of current programs or activities addressing the fifth principle—"Public health should seek the information needed to implement effective policies and programs that protect and promote health." Similarly, they did not recognize alignment with their agency's mission and the ninth principle—"Public health programs and policies should be implemented in a manner that most enhances the physical and social environment." While they acknowledged that NIH-funded research results may indeed be used to address these principles, the focus on implementation of programs did not seem to fit with the agency's primary focus on basic research. While the agency officials interviewed for this study do see general alignment for the code's principles, they have also raised some question about the value of the code to an agency whose mission is predominantly focused on biomedical research, a topic discussed in greater detail in later findings of this study. One NIH official expressed that although the code's principles are important and in many ways related to the agency's work, if the code were to be used at NIH, the principles may have to be reframed to fit more directly in an environment where research, as opposed to implementation of public health programs is the focus.

Key Question 2: To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?

Key finding 2.1: Familiarity with the public health code of ethics varied dramatically between agencies: All CDC officials and associates interviewed for this study were familiar with the public health code of ethics, and none of the NIH officials had seen or heard of the code before being interviewed for this study

Of the CDC officials and associates interviewed for this study, all of them were familiar with the public health code of ethics and had used it in the course of their work with the agency. One interviewee who chairs the CDC Public Health Ethics Committee noted that the code was used in the agency's discussion paper on public health ethics as a tool to articulate the ethical foundation for the practice of public health. Another official had worked with the code as the CDC developed ethical guidances on the topics of collection, storage, and use of data not only for its staff, but also for its grantees and other external partners saying,

> "we made use of this set of principles as we were developing and thinking about how we would operationalize some of the tasks that we needed to put into very specific guidance for our partners, not just our internal scientists and public health practitioners but also folks with whom we work out in the states. So this set of principles as well as the rest of the work of the Public Health Leadership Society was extremely helpful for us in terms of having some context and some background for us to kind of ground how we were going to operationalize some of the principles for our partners."

In addition to those who reported using the code in their work, some officials at CDC had been involved in the development of the code or were a part of the agency's conversation about whether to formally adopt or endorse it, discussed in detail in the next finding.

In stark contrast to the CDC officials' familiarity with the code, none of the NIH officials interviewed had heard of the code prior to being interviewed for this study. One official noted that despite being a member of the APHA, the official had not been familiar with the code, but did not think that was particularly unusual. The key informant drew a parallel with a set of guidelines developed for core competencies in the field of gemonics developed by APHA, saying

that these competencies have also not been disseminated widely and therefore not necessarily

known to those in the field. The official noted,

> "I think this is not an uncommon thing to happen, but sometimes, within the governance
> structure of an association as large as APHA, principles or guidelines or declarations are
> made through the governance process but are not disseminated in a broad way… I do
> think that there is information here in some of the principles that clearly could be of value
> to the government, both CDC and NIH, with regards to the framing of public health
> issues and ethical principles."

Despite the fact that all of the NIH officials interviewed for this study were involved in ethics

programs and activities at the agency, none had familiarity with the code. As a result, they were

also unaware of any effort to or discussion about the agency adopting it formally or using it in

any way within its ethics programs. Because the key informants from NIH are senior leaders

involved in the agency's ethics programs, they are in a position to know whether such a

discussion were underway at the agency.   Therefore, for the purpose of this study, we will

conclude that NIH has not considered formal adoption of the code.

When asked whether the code would be a useful tool for the agency, NIH officials responded

with mixed opinions. One official indicated that there might be a potential benefit to using it to

"help keep everyone's focus and to serve as a good reminder that we're a public health agency

and not an academic institution." Another noted that "no one could argue with any of these

principles that they are all important. I think you can reframe them to fit into a research

environment of NIH." When asked whether the code might add any benefit to the agency's

ethics program, one official responded, "I guess I would address it much more on where are the

problems and what is needed from a regulatory perspective to address those problems to enhance

the practice within the field of biomedical research and the ethical practice. So it's less about

creating a set of principles and it's more about what do we really need to do from an applied

perspective to make sure that actually, those types of principles are being implemented in an

appropriate way?" While none of the key informants doubted that the principles were sound and were generally relevant to the agency's work, there was no consensus on whether the code would be a useful tool in a formal or informal way.

Key finding 2.2: The CDC has considered formally adopting the code and has declined to do so

CDC officials said that there had been discussions in the agency about whether to formally adopt the public health code of ethics which resulted in a decision not to do so. One official described internal disagreement over whether formal adoption of the code would be necessary or beneficial given that many view the code as one tool among many to use in articulating the agency's view on public health ethics. The official noted that, "I think that there's dispute over whether that would be a good thing or not because I think our approach is that we view the code… as something that is useful but we don't really think it's useful to say this is the one code that we will live by. So instead, we want to see it as a tool along with other types of tools that could be useful."

Another agency official described the decision not to formally adopt the code as less a deliberate rejection of the idea and more of a case of the issue being debated, but just not resolved, resulting in the agency not taking action to adopt the code. The key informant noted that a small group of the CDC leadership team discussed the matter on more than one occasion, specifically talking about what it would mean for the agency to make a formal endorsement or adoption of the code and specifically what the legal implications would be for such an action. "These discussions went on with a small group of people within the agency and it just ended up not getting to the priority level to solve. It never came to resolution whether we would or would not. There was

no compelling reason to or not to formally endorse [the code]." The official went on to describe

the fact that whether the code is formally adopted by the agency may not matter in terms of its

use and its relevance to the agency's work. Because a number of CDC officials who currently

work in the area of ethics had involvement in the code's development, this official said their

support of the principles it contains can be assumed. In addition, since many have worked with

or are members of the organizations that developed or adopted the code, for many staff members,

acceptance of the principles has occurred outside of the agency. One official stated that,

> "Most of the people who work in public health and who work at CDC are involved with
> APHA and many of us have done work with the Public Health Leadership Society. Many
> of us already have adopted these principles and these ethical values, as part of our
> membership in these other organizations. It didn't seem compelling or absolutely
> necessary for us to make any statement on adopting these specifically for CDC. In
> addition to that, our work with developing them, in many ways I think, sent signals about
> our belief in what they stood for."

Within the CDC, while there appears to be wide acceptance of the code and agreement that its

principles are relevant to the agency's work, there is resistance to formally adopting it. One

interviewee described this by noting, "I think that there is acceptance that it is a useful tool for

our work but I think people stopped short of saying… that this is the one code that we all live by.

I think people will probably find that too limiting." Resistance to formally adopting the code

may exist in part because the principles align so closely to the mission and work of the agency

and because so many of the ethics officials were involved in the code's development or have

accepted the code professionally through other organizations like the APHA that have adopted it.

One official recognized this, saying, "It's something that is so ubiquitous around our work that

there's hardly any reason to formally do anything about that. And there were so many people

already involved with this kind of work, [who] have membership groups that have adopted this

as their ethical mantra, that perhaps most of us already see this as part of the way we function."

Although CDC has not formally adopted the code, it features prominently in the discussion paper which serves as the agency's framework for public health ethics .(CDC Public Health Ethics Committee, 2007) In addition, agency officials noted that CDC uses the code as a basis for web-based training it is developing for agency staff to provide a foundation and common understanding about what public health ethics is and how it applies to the practice of public health. One official noted that, "there is a module that deals with the values in public health and then another module that deals with the ethical principles and that's really coming from the document, *Principles of Ethical Practice of Public Health*."

Key finding 2.3: Officials at both agencies identified potential barriers to adopting the code leading to mixed opinions about the benefit of doing so

Officials from CDC and NIH identified several barriers to using the public health code of ethics in their agencies. In general, these barriers fell into two broad categories: 1) legal issues and agency authority and 2) justifying the need for the code. Within these categories, in some cases, officials from both agencies identified similar barriers, while in other cases, those from NIH raised issues unique to their agency.

Subfinding 2.3.a: CDC and NIH officials identified legal obligation and agency authority as barriers to adopting the code.

Key informants from both agencies discussed the issue of legal obligation and agency authority as potential barriers to formally adopting a code of ethics for an agency. One CDC official noted that the leadership group that convened to discuss the possibility of formalizing the code at CDC specifically discussed the legal obligations that may come with adopting or endorsing a particular code of ethics. While the group did not resolve this issue, it raised the question of

what the agency's legal obligation would be to enforce the code if it was adopted. In other words, it asked what consequences the agency would bring to bear in the event that an employee did not act in accordance with the code when carrying out the agency's work. One official offered an example, asking, "What is our responsibility to enforce number 11 [the principle regarding ensuring professional competence]. What if one of our employees does something that proves or shows they're professionally not competent, what is our legal responsibility then?" She used this example to highlight that questions of accountability and enforcement would have to be resolved before the agency could consider formally adopting the code. In addition, she noted that consideration would have to be given to whether the agency would be obligated, or choose to, enforce these principles with its contractors, grantees, and other partners it engages for public health activities. The agency conducts only a portion of its public health mission through its employees. A major portion of its budget goes to funding public health work through grantees, contractors, and other entities it funds to carry out the agency's mission. Would adopting the code mean enforcing it among CDC employees and all of the agency's funded entities? Does the agency have the legal authority to do so? The leadership group at CDC acknowledged that it raised but did not resolve these important questions. Agency officials noted that if the issue of formally adopting the code is to be revisited, these questions would have to be addressed and a means of enforcement would have to be put in place.

Key informants at NIH raised similar questions about authority and legal considerations when asked about barriers to formally adopting the code, but made a distinction between accepting aspirations within a code of ethics and translating them into policy. One official at the agency put it this way, "the problem is not so much in terms of [the code's] aspirations. The problem could be related to proposed implementation of programs or activities to achieve those

aspirations." The official used the agency's assessment of conflict of interest to illustrate the point. The Standards of Ethical Conduct that apply to all federal employees include provisions regarding employees' conflict of interest. As a result, the agency has put into place a system and policies for meeting its obligation to assess and address conflict of interest among its employees, including requirements for employees to disclose certain financial information. The official notes that,

> "Part of the way we address conflicts of interest is through the financial disclosure system. But the financial disclosure system is described for us by regulation and we cannot ask our employees for and collect from them information about their financial and other relationships that goes beyond that which we are permitted to request under the regulation. So that if there were found to be concerns that we were missing something or we weren't asking a question that would get at some other information of value, we could not independently just start doing so. We have to go to a regulatory or statutory process in order to gain permission to do so."

This example points to the fact that acceptance of the code's principles is one thing, but to formalize it in a way that required employees to follow it, may require the agency to seek additional legal authority to enforce it. According to one key informant, "The devil is always in the details of how we are able to say objectively we're achieving this goal—or to develop a measure against which we can say 'No, we're not.'" Obtaining the authority to enforce the principles of the code is an activity outside of the agency's control and would need to be considered before it could adopt a set of principles such as those found in the public health code of ethics.

Subfinding 2.3.b: CDC and NIH officials recognized the lack of a clearly articulated rationale for the code as a barrier to its adoption.

Officials at both agencies discussed the importance of articulating a clear rationale for using the code. They agreed that the absence of a clear and convincing justification for the code would be a significant barrier to having it used in the agency. In general, the comments from key

informants indicated that no matter how well-intentioned the code's creators are and how

agreeable the basic principles are, without providing specific rationale for how it can improve an

agency's programs and quality of work, it will not be successfully adopted or used at CDC or

NIH. One CDC official who thinks the code would be useful to the agency said,

> "we need to really be able to demonstrate to people that what we're trying to do on public
> health ethics can make a change in our programs. I think some people, if you can't sort of
> objectively identify what your impact is then they may be a little hesitant wanting to
> adopt what you're talking about."

In contrast to this official's implied advocacy for the code's use at CDC, an official from NIH

was not convinced of the need for the code. Despite finding the principles reasonable, this

official is unclear about how using the code would improve the work of NIH saying, "the

principles that are enunciated on this list of twelve— there's nothing about any of them that I

would say is objectionable or wouldn't be useful in some way, but I don't know that having this

particular list of twelve would make any difference in terms of the way people do things." The

key informant noted that although several of the principles are directly related to the work at

NIH, the value of endorsing a code of ethics for public health is not obvious. Specifically, the

official notes of several of the topics addressed in the code, "these are things that the NIH

basically does pay attention to. Whether or not it would help them to have this list of 12 in front

of them? It's hard to see that it would make much difference, I have to say."

Another NIH ethics official expressed a slightly different opinion about the value of committing

to a set of principles to guide expectations about employees' work and ethical practice, noting "I

always think that's it's extremely important for there to be dialogue and conversation about what

is expected and having framing principles is extremely important." When asked specifically

about the value of the public health code of ethics to the agency, the official was not certain, and

echoed concerns from other key informants about the agency's authority to enforce a particular

set of principles saying, "If [the code] is to be used as principles to help to frame boundaries and how an agency or an individual does work, then ultimately they must get transferred into actual rules and regulations. And so my question would be what are we trying to solve and what is the issue at NIH that we would be seeking to solve and does this set of principles actually do that or is there something that is framed in a different way that would be valuable?" This comment raises questions about whether the code is directly relevant to the workforce at NIH and whether it would fill a void in current ethics programs and policy.

Several of the key informants from NIH questioned whether NIH was really a "public health agency." Although the agency falls within the federal government's Public Health Service, NIH officials more readily identified the work of CDC and others within the U.S Public Health Service as more directly related and devoted to traditional "public health" work than NIH which they consider more focused on basic biological research and discovery. One official noted that although there is general alignment of the public health code of ethics with NIH's work, the collected set of principles may not have a place in the agency given the focus on program implementation rather than research saying,

> "The National Institutes of Health's mission is to discover new information that will help to reduce the burden of disease and improve health so clearly, the issue of the public impact is important to the work of NIH. But in reality, we are not a public health agency from what I would consider a traditional public health agency. I clearly think that CDC has that role and even HRSA (Health Resources and Services Administration) has some of that role within the federal government and really NIH's primary mission is the discovery of new knowledge to help to improve the health and reduce the burden of disease. But one of the questions whenever you look at a grant application or a new protocol is, what is the public health impact described in the work that they're doing?"

All of the NIH officials interviewed for this study acknowledged that there is public health work that results from the research at NIH, but in terms of the culture and the way workers within that agency view their mission, many of them questioned the accuracy of calling the agency a "public health agency," and by extension, questioned the value of adopting a code of ethics for public

health at an institution that does not necessarily see itself as an agency with public health at the core of its mission and purpose.

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Key Question 3: If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?

Key Finding 3.1: The CDC and NIH each has a process for considering additions or changes to agency ethics programs which would allow gaps in their programs to be addressed

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Interviews with CDC and NIH officials revealed that both agencies have clearly defined procedures for considering changes to their respective ethics programs and policies. Key informants were asked to describe their agency's process for making changes to their ethics policies and who the decision-makers are when new information or resources are presented for consideration. Both agencies have multiple levels of ethics rules to which their employees are accountable, including rules at the federal, department, and agency levels. In addition, key informants from both agencies described multi-pronged approaches to training employees regarding ethics rules and several channels through which employees can learn about and seek support for ethical dilemmas or questions that arise during the course of their work.

CDC: Process for change

CDC officials interviewed for this study noted that following the agency's re-organization under former CDC Director, Dr. Julie Gerberding, and the subsequent appointment of Dr. Thomas Frieden as Director in 2009, the decision-making for high level policy changes such as to the ethics program has changed. At the time the agency was considering adopting the code, there were three groups involved in the discussion and decision-making: the Executive Leadership Board, the Scientific and Center Leadership group, and the Business and Management

Leadership group. First, the Executive Leadership Board consisted of the scientific and management executive leaders at CDC, all of whom reported to the Director's Office and ran the executive decision-making of the agency. Next, the Scientific and Center Leadership group was comprised of scientific leaders at the agency who ran and were responsible for the center-specific subject matter for what were at the time twelve centers within the agency with anywhere from a few hundred to a few thousand people and scientists and program people within their purview. The twelve Center Directors formed this group which had some decision-making power in the area of ethics policy. Finally, the Business and Management Leadership group was made up of representatives from each Center with expertise in the administrative aspects of the Centers. Collectively, these three groups would, in some combination, discuss and make decisions about high-level issues such as policy changes for the agency's ethics programs. One official noted that " often these groups would consult other groups whether they were scientific leaders or other kinds of leaders that were deeper in the organization about specific issues, but ultimately, that kind of CDC endorsement [of the public health code of ethics] would come from a decision made from these three leadership groups." Further, the official added, "It's interesting because when we first talked about whether we would adopt this, we were under the leadership of our previous [Director] and our previous organizational structure. We have recently had a new agency director appointed and that agency director has re-organized the Office of the Director of the agency and now new structures are in place in terms of who makes what kind of decisions." This key informant acknowledged that at the time this issue was debated, the new decision-making structures put into place by the Director "were not operating to full speed yet." So, if the issue had been put up for a final decision, it would have been considered under the process described earlier, through the three decision-making bodies at CDC.

When asked about the current process, if the decision to adopt the code should come up again for consideration, officials noted that it would likely be decided in a more centralized manner within the Office of the Director of CDC, but with input from the same groups of leaders. One official explained it like this:

> "Now, things are different and a decision like this would likely be made through the director with some advice from his immediate leadership team which consists mostly of the directors from the centers and his close leadership team which includes a group of people who are deputy directors for program and science and policy and his associate directors on those topics as well. So it's a similar kind of structure. They're called different things but ultimately it's the same level of leadership that would make this kind of decision."

The official noted, however, that under the agency's new leadership, the issue of adopting the code has not emerged as a priority as it had been under the previous Director. One agency official stated that "With our old director, this was something that very much was setting the stage and being sure that we had a lot of visibility and leadership around, public health ethics was very important and we definitely… these issues were very much on the radar screen and extremely visible." In contract, the official noted that currently it has not been a priority and is not an issue that has been brought back to the table for re-consideration.

NIH: Process for change

NIH officials interviewed for this study provided insights into the process by which changes to the ethics policies or programs would occur at the agency and any barriers that might exist to making such changes. Because the agency does not make a distinction in its ethics programs between research ethics and public health ethics as the CDC does, the process for change specifically regarding public health ethical principles is not entirely clear. However, a discussion of policy review and change in general for NIH could serve as a guide to understanding or

approaching changes one might propose for public health ethics. The descriptions of the process for introducing a change varied across NIH officials interviewed for this study and are summarized in this section.

One official described what the process would be for changing agency-level policies regarding ethics saying that "I guess the starting point would most likely be in the NIH Ethics Office and then I'd raise it internally to the deputy director for policy and procedure." This official gave an example of a change to ethics rules that followed that path when agency leadership felt it was appropriate to create a more rigorous ethics training requirement for staff than what was mandated by law. Whereas there was a regulation stating that only certain staff had to be trained annually in ethics procedures—which amounted to approximately half of the NIH workforce— the agency leadership believed that all staff should receive annual training. As a result, the agency created its current policy that all staff are trained annually in ethics procedures. That policy came about because the agency determined that it wanted to put into place a more stringent policy than what the regulations required. This official said that the agency is at liberty to change ethics policy if, at a minimum, the regulations governing ethics are satisfied, further noting that "the government-wide rules are the floor, so any policy we would put out would have to be raising the bar." This key informant said that there is a flow of feedback from the institutes and centers to the central NIH Ethics Office that can and does result in policy changes. The official noted that because the office meets regularly with the Ethics Officers from each institute and center, "they're constantly giving feedback on how they feel procedures and policies are working and we take that very much to heart and we're revising our policies all the time to try to reflect often the very great input that we get from them."

Another official explained that for policies that are related to the ethical practice of research, the Office of the Director of Intramural Research would have authority to consider and implement changes for the agency. Within that office, the NIH Scientific Integrity and Ethics Committee is responsible for scientific conduct and misconduct and scientific integrity among intramural staff. The official explained that in addition, the Committee "oversees, in a general way, the conduct and research courses that every branch, every laboratory is required to have." Then, at the institute level, every institute has an ethics officer and some have an ethics office both of which are tasked with monitoring and supporting employees' compliance with the federal standards for ethical conduct or, as one official described it "what the employees at their institute can and can't do." They oversee how agency employees do research and whether they follow the ethics guidelines that are laid out in the regulations. In addition, there is the Office of Extramural Research which ensures that all extramural researchers funded by the agency follow the regulations and the ethics rules.

Another official described his understanding of the process for change like this: "My interpretation of it is that really, the direction comes from a central level and then it's kind of distributed out to the [institutes and centers], and they may translate that or actually implement it in unique ways to their environment." This official further noted that within the intramural program, there is a governance process where investigators, working with the scientific directors in the agency have the ability to offer policy recommendations and raise issues of importance to the intramural program for consideration by the agency. Yet another official indicated that the process for change might vary depending on the issue or topic area, noting that

> "I think it would depend on the topic. If an individual has a suggestion or thoughts about how the current ethics program is being managed or implemented, they are usually not shy about letting us know and they would go to program officials with their feedback. If an individual has an idea about something that is not addressed at all but they think that it

should be, the policymakers might depend, again, on the precise topic because there are at times policy decisions have to be made by NIH in consultation with the Department of Health and Human Services, and at other times, they can be made just within NIH."

In summary, agency officials indicated that there is no single, clearly established process for ethics policy change at NIH, but rather multiple routes for receiving feedback and suggestions and ultimately for making a policy change.

Section II: Document Review Findings

Description of sources

The documentation review for this study began with a search of publicly available information and was supplemented by material collected from key informants. Both CDC and NIH maintain extensive web sites containing information on their respective ethics programs. Of the many published documents pertaining to ethics activities and programs at the agencies, there were a few that were key to the findings derived for this study. From the CDC, a discussion paper published by the agency's Public Health Ethics Committee provides an introduction to public health ethics, discusses the public health code of ethics as a foundation for public health practice, outlines the mission and goals of the agency's public health ethics activities, provides an organizational overview of the agency's ethics resources, and details the agency's training and consultation for public health ethics(CDC Public Health Ethics Committee, 2007). The agency's ethics web page also provided details regarding specific ethics policies and training opportunities for staff.   From the NIH, the agency's internal introduction to government ethics outlines the principles of ethical conduct, discusses conflicts of interest, provides examples of ethical dilemmas and how government ethics rules apply, and identifies agency resources for a variety

of ethics questions and issues(National Institutes of Health Ethics Office, 2009). Also from NIH,

its web pages on the agency's Public Trust Initiative and individual institute and center pages

provided details about programs and activities that relate to the principles in the public health

code of ethics. In addition, reports from the GAO and the CRS provided background and

description of public health service agency organizational structure and ethics activities

(Congressional Research Service, 2005; U.S. Government Accountability Office, April 30, 2007;

U.S. Government Accountability Office, September 30, 2008).

Key Findings

Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?

Key finding 1.2: There are programs at CDC and NIH that address most of the 12 principles of the public health code of ethics.

Both the CDC and NIH publish extensive resources pertaining to their organizational structure,

programs, research, and policies on their web sites for the public. Both agencies make available

to the public documents that indicate robust ethics programs and activities including offices or

divisions devoted to the topic of ethics, regular ethics committee meetings, programs designed to

solicit public input into agency priorities (in the case of NIH), policies regarding protection of

populations involved in research, and programs designed to communicate and share agency

research and knowledge with various publics. A search of each agency's web site and other

publicly available documents revealed programs, practices, guidelines, or organizational

components that address most of the 12 principles in the public health code of ethics. However,

in a few instances, the search did not yield information to address or fully address the code's

principles. A summary of results from this review of documentation is presented in Table 7, with a discussion of those findings following.

Components, Programs, and Policies Addressing the Code of Ethics Principles

Table 7 provides a summary of the publicly available information regarding the agencies' organizational components, programs, policies, and other activities that address the 12 principles in the public health code of ethics. Each agency maintains a web site with numerous resources for the public to access research results, information, and tools funded by taxpayers and created in fulfillment of their respective missions. Several specific components, programs, and policies displayed in Table 7 address more than one of the principles. All components are indicated in bold and are defined or described, by agency, in the narrative that follows. Following the discussion of these components, programs, and policies, is a summary of potential gaps between agency practice and the code's principles.

Table 7: Publicly Available Information on CDC and NIH Components, Programs, and Policies Addressing the Public Health Code of Ethics Principles

Public Health Code of Ethics Principles[a]	CDC Elements Addressing Principles	NIH Elements Addressing Principles	Potential Gaps?
1) Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes	• Agency mission and goals • National Center for Chronic Disease Prevention and Health Promotion	• Agency mission and goals • Office of Disease Prevention	**NO**
2) Public health should achieve community health in a way that respects the rights of individuals in the community	• Human Research Protection Office • Agency pledge	• Office of Extramural Research: Research w Human Subjects	**NO**
3) Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members	• **None found for agency-wide policy or process for obtaining community input**	• Council of Public Representatives (COPR)	**YES for CDC**
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	• Office of Minority Health and Health Disparities • CDC/ATSDR Minority Initiatives Coordinating Committee • National Center for Chronic Disease Prevention and Health Promotion	• Office of Research on Women's Health • National institute on Minority Health and Health Disparities	**NO**
5) Public health should seek the information needed to implement effective policies and programs that protect and promote health	• Agency mission and goals	• Agency mission and goals	**NO**
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	• HealthComm Key • **None found for "community consent" for implementation**	• Public access to research results • **None found for "community consent"**	**Partial for CDC &NIH**
7) Public health institutions should act in a timely manner on the information they have within the resources & mandate given to them by the public	• National Center for Chronic Disease Prevention and Health Promotion	• Public access to research results	**NO**
8) Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community	• Office of Minority Health and Health Disparities • CDC/ATSDR Minority Initiatives Committee	• COPR • National Institute on Minority Health and Health Disparities	**NO**
9) Public health programs and policies should be implemented in a manner that most enhances the physical and social environment	• Healthy Community Design • National Environmental Policy Act involvement	• **None found**	**YES for NIH**
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 signif. harm to the individual or others	• Health & Human Rights Workgroup	• Office of Extramural Research: Research Involving Human Subjects	**NO**
11) Public health institutions should ensure the professional competence of their employees	• PHEC on Education for staff • Education Strategic Plan	• Annual ethics training for perm. employees	**NO**
12) Public health institutions & employees should engage in collaborations & affiliations in ways that build the public's trust & institution's effectiveness.	• Agency pledge	• Agency goals • COPR • Public Trust Initiative	**NO**

[a] *Principles of the Ethical Practice of Public Health*, Public Health Leadership Institute, 2002.

Subfinding 1.2.a: CDC documents show that the agency has programs and activities that address most of the principles in the code of ethics

The **CDC's mission, goals, and pledge** address the code's principles 1, 2, 5, and 12 and are

supported and carried out by the agency's component organizations. The agency is undergoing a

reorganization of its structure into 20 Centers, Institutes, and Offices that are tasked with

carrying out the agency's mission and goals which are stated as follows:

> "CDC Mission: Collaborating to create the expertise, information, and tools that people
> and communities need to protect their health – through health promotion, prevention of
> disease, injury and disability, and preparedness for new health threats.
>
> Goals: CDC seeks to accomplish its mission by working with partners throughout the
> nation and the world to monitor health, detect and investigate health problems, conduct
> research to enhance prevention, develop and advocate sound public health policies,
> implement prevention strategies, promote healthy behaviors, foster safe and healthful
> environments, and provide leadership and training" (Centers for Disease Control and
> Prevention).

The agency's mission, with a focus on prevention of disease, injury, and disability—adverse

health outcomes—provides a clear link to the first principle. In addition, by striving to deliver

the knowledge and resources "communities need to protect their health," the agency mission

speaks directly to the idea of addressing the "requirements for health" as the first principle

encourages. One example of how the agency has implemented its mission is through the "CDC

for You" segment of its website. This element of the home page of CDC's website includes

links to pages designed to relay agency information and resources to a variety of publics

including: individuals in the general public, public health professionals, healthcare providers,

students and educators, researchers, members of the media, policy makers, and businesses, thus

addressing the agency's mission "to create the expertise, information, and tools that people and

communities need to protect their health" (Centers for Disease Control and Prevention).

One of the agency's Centers in particular—the **National Center for Chronic Disease Prevention and Health Promotion** —has a mission that addresses principle 1 directly, in that it is tasked with "leading efforts that promote health and well-being through prevention and control of chronic diseases" (Centers for Disease Control and Prevention). The Center's five strategic priorities further support the intention of the first principle as well as principles 4 and 7:

> "1) Focus on Well-Being: Increase emphasis on promoting health and preventing risk factors, thereby reducing the onset of chronic health conditions.
>
> 2) Health Equity: Leverage program and policy activities, build partner capacities, and establish tailored interventions to help eliminate health disparities.
>
> 3) Research Translation: Accelerate the translation of scientific findings into community practice to protect the health of people where they live, work, learn, and play.
>
> 4) Policy Promotion: Promote social, environmental, policy, and systems approaches that support healthy living for individuals, families, and communities.
>
> 5) Workforce Development: Develop a skilled, diverse, and dynamic public health workforce and network of partners to promote health and prevent chronic disease at the national, state, and local levels" (Centers for Disease Control and Prevention).

The Center's focus on well-being and reduction of chronic diseases further supports principle one, while the activities to ensure health equity address the fourth principle which encourages public health institutions to "work for the empowerment of disenfranchised community members." The code's seventh principle suggests that "public health institutions should act in a timely manner on the information they have" —an idea which is supported by the Center's strategic priority to "accelerate the translation of scientific findings into community practice."

The agency-wide goals that CDC has established for achieving its mission make explicit the agency's responsibility not only to generate the knowledge and tools needed to assist communities, but also "to implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training" which are tasks advised by the fifth principle. In addition to the mission and goals, the agency pledges to the American

people, "to be a diligent steward of the funds entrusted to it; to provide an environment for intellectual and personal growth and integrity; to base all public health decisions on the highest quality scientific data, openly and objectively derived; to place the benefits to society above the benefits to the institution; and to treat all persons with dignity, honesty, and respect" (Centers for Disease Control and Prevention). Its promise to be a "diligent steward" of the taxpayer funding it receives to carry out its work addresses a key element of principle twelve which encourages public health institutions to conduct its work "in ways that build the public's trust." Finally, its pledge to "treat all persons with dignity, honesty, and respect" indicates the agency's desire to engage with individuals in the communities it serves in the way that principle 2 encourages by achieving community health with "respect for the rights of individuals in the community."

The CDC's **Human Research Protection Office** is another entity that addresses principle 2 in that its mission 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 (IRB), and through relationships with external partners" (Centers for Disease Control and Prevention). Any domestic or international research that is conducted by or funded by the agency must adhere to the Department of Health and Human Services' Policy for Protection of Human Research Subjects, and most research involving human subjects must be approved by an IRB. The Human Research Protection Office ensures that these policies are followed and facilitates the process of application to the IRB. This component of CDC serves to protect the rights of individuals in the community who are participants in health research as advised by principle 2.

There are two bodies within the agency that address the ideas espoused in principle 4 regarding advocacy and work for "the empowerment of disenfranchised community members" in order to

"ensure that the basic resources and conditions necessary for health are accessible to all" and in principle 8 which advises incorporating "a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community." The first is the **Office of Minority Health and Health Disparities** which aims in part 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" (Centers for Disease Control and Prevention). The office's activities include promotion of minority health with the goal of eliminating racial and ethnic health disparities and development of agency-wide policies, strategies, and programs to address minority health. The second body is the **CDC/ATSDR Minority Initiatives Coordinating Committee** which coordinates all the Department of Health and Human Services' initiatives to address minority health within the agency. In addition, the Committee "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" (Centers for Disease Control and Prevention). The committee includes representatives from each of the agency's Centers.

The sixth principle advises institutions to offer communities information "needed for decisions on policies or programs." The CDC sponsors **HealthComm Key,** a program developed by Emory University that addresses this aspect of the principle. The program is a searchable database that summarizes health communication studies that have been peer-reviewed and published (Centers for Disease Control and Prevention). This resource could be used to help communities access information from previous studies and evaluations that can be helpful for

decision-making for public health programs by applying findings from the published studies included in the database.

The ninth principle advises that "public health programs and policies should be implemented in a manner that most enhances the physical and social environment." The CDC addresses this principle with its **Healthy Community Design** web site which offers a variety of resources designed to assist communities in addressing the affects of the built environment on public health. The resources include links to information on climate change, healthy community design, and health impact assessments to help communities determine a program's impact on the environment (Centers for Disease Control and Prevention). In addition, the agency has a role in carrying out the portion of the 1970 **National Environmental Policy Act**[8] that requires federal agencies to consider the impact of its plans and programs on the environment. The agencies must conduct an environmental impact assessment to review "the potential effect its initiatives might have on the nation's social, economic, and natural resources" (Centers for Disease Control and Prevention). Depending upon the results of this preliminary assessment, the agency may need to engage in a more detailed analysis and plan to address the impact of its programs. The CDC participates in this environmental impact assessment process by reviewing and providing comments on submissions by other agencies—a responsibility the Department of Health and Human Services delegated to the agency.

The CDC's **Health & Human Rights Workgroup** helps to address principle 10 which encourages institutions to "protect the confidentiality of information that can bring harm to an individual or community if made public." In general terms, the Workgroup provides training to

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[8] 42 U.S.C. §4321.

public health professionals "about health and human rights principles and the methods for incorporating these principles into public health practice" (CDC Public Health Ethics Committee, 2007) which addresses the tenth principle's suggestion that public health institutions operate in a way that offers protection for those who participate in its research and programs. The Workgroup's activities include "hosting seminars and workshops, co-sponsoring conferences, developing a compendium of resources, and collaborating with other groups on related issues" (CDC Public Health Ethics Committee, 2007).

 While the agency has several programs and activities in place that address the education of its workforce—as principle 11 suggests—there is one coordinating body that serves as an example for coordination and planning workforce training in the area of public health ethics and "ensuring the professional competence of their employees." The **Public Health Ethics Committee's Education Subcommittee** develops CDC capacity in public health ethics by coordinating the following activities: "assessing CDC resources, needs and competency relating to public health ethics; planning educational programs in public health ethics for CDC staff; conducting trainings, workshops, and seminars; evaluating public health ethics educational and training activities; and collaborating with other CDC groups on public health ethics- related educational activities" (CDC Public Health Ethics Committee, 2007). The Subcommittee aims to increase public health ethics competency among its members and among agency staff by conducting a variety of trainings and activities in public health ethics, supporting research in this area, and evaluating the agency's public health ethics activities. In addition, the Subcommittee develops an Education Strategic Plan to plan and outline its activities in this area.

Subfinding 1.2.b: NIH documents show that the agency has programs and activities that address most of the principles in the code of ethics

The **NIH's mission and goals** directly address the public health code of ethics' principles 1, 5, and 12 and are carried out by the agency's 27 institutes and centers, each with its own mission, budget, and research agenda. These organizational components conduct, coordinate, fund, or support health research for the agency and are tasked with carrying out its mission and goals which are as follows:

> "NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.
>
> The goals of the agency are:
>
> - to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
> - to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
> - to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
> - to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science" (National Institutes of Health).

The agency's mission "to seek fundamental knowledge about the nature and behavior of living systems" directly addresses the code's first principle which encourages institutions to address "… the fundamental causes of disease and requirements for health." In addition, the goals for the agency reinforce this principle as well as the fifth principle—to seek the information needed to implement effective policies and programs that protect and promote health—with their focus on the application of research for "protecting and improving health" and to "ensure the nation's capacity to prevent disease." The agency goals to ensure a high return on financial investment and to promote scientific integrity and public accountability address the twelfth principle which states that institutions should conduct their activities in ways "that build the public's trust and the institution's effectiveness" by stressing the importance of fiscal responsibility and accountability to the taxpayers who fund the research carried out by the agency. In addition to the agency

mission and goals, **NIH's Office of Disease Prevention** addresses the first principle in the code with its mission to "foster, coordinate, and assess prevention and health promotion research as part of the NIH effort to improve public health, reduce disease burden, and improve the quality of life for all Americans," thus paralleling the code's focus on "aiming to prevent adverse health outcomes" (National Institutes of Health).

The **Office of Extramural Research** addresses the code's second principle regarding respect for the rights of individuals in the community and its tenth principle regarding protection of confidentiality for individuals with its program for the protection of human research subjects. The program web site gathers in one place a number of resources for researchers engaged in work involving human subjects and provides links to training resources, regulations, agency policies, and special considerations for vulnerable populations. For example, the site provides links to two training videos produced by NIH for the research community on current regulations for the protection of human research subjects and the use of their private information and how to report unexpected problems or adverse events when conducting research with human subjects. Researchers and others are welcomed to use and reproduce the videos as training resources in their own workplaces and research communities (National Institutes of Health).

The NIH Director's **Council of Public Representatives (COPR)** is an advisory body whose activities address the code's third, eighth, and twelfth principles. The COPR is comprised of members of the public who provide feedback and advice to the Director of NIH on a range of issues including NIH research priorities, outreach, and other topics of interest to the public. It is the agency's formal mechanism for obtaining public input into its activities. Annually, the agency selects new members to serve on the COPR for an average of four years and aims to populate the COPR with members who represent diverse cultural, professional, and geographic

perspectives. This program helps to ensure that the agency's policies, programs, and priorities are developed with input from community members and that NIH incorporates input that respects "diverse values, beliefs, and cultures in the community" as the third and eighth principles encourage. The COPR states that its goals include "serving as the public's voice on issues relating to NIH's mission, informing the public of the research and health benefits gained through the public's investment in NIH, and helping NIH understand the public perspective and engage the public in NIH activities" (National Institutes of Health). This serves as part of the agency's means of engaging the public in its work, communicating its effectiveness to the public, and building trust among the communities it serves which is consistent with the twelfth principle.

There are two components of NIH that address the forth principle in the code of ethics which encourages public health to "advocate and work for the empowerment of disenfranchised community members" and ensuring access to the conditions needed for health. First, the **Office of Research on Women's Health** serves as a focal point for women's health research at the NIH. Under the purview of the NIH Director, the Office supports the agency's role in improving women's health by coordinating research on the effects of gender on health, partnering with the institutes and centers within NIH to ensure that research on women's health is built into the research priorities across the agency, and provides advice to the NIH Director regarding women's health research (National Institutes of Health). Second, the **National Institute on Minority Health and Health Disparities (NIMHD)** addresses this principle as well as the eighth principle regarding respect for diverse values and cultures in the community through its vision and mission:

> "The NIMHD envisions an America in which all populations will have an equal opportunity to live long, healthy and productive lives. The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to promote minority

health and to lead, coordinate, support, and assess the NIH effort to reduce and ultimately eliminate health disparities" (National Institutes of Health).

To fulfill its mission, the NIMHD conducts and supports research on, training about, and outreach to minority communities and others adversely affected by health disparities. Like the Office of Women's Health research, the NIMHD collaborates with the institutes and centers at NIH to ensure that the research agendas across the agency adequately address health disparities. In addition, the Institute works to ensure that the agency is engaging in dissemination of research results to the communities affected by health disparities.

The NIH's **Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research**, which became effective in May 2005, addresses the sixth and seventh principles in the code which instruct public health institutions to provide information to communities for use in decision-making for policies and programs and to act in a timely manner on the information they have. The public access policy was developed after a process of public hearings and comments solicited from the public, publishers, researchers, health care professionals, academics, and others with an interest in the accessibility of research results to the public. The policy asks NIH-funded investigators to submit an electronic version of final research manuscripts to the NIH's National Library of Medicine for inclusion in the searchable PubMed database which is a publicly available collection of research results. The agency describes three main goals of the policy:

> "1) create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; 2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and 3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists" (National Institutes of Health).

The policy pertains to authors whose research was funded completely or in part by NIH and asks that authors submit their work for inclusion in PubMed at the time a manuscript is accepted for publication, thus ensuring that results are available quickly to the public.

The **NIH's ethics manual,** "Without Integrity Nothing Works," includes details regarding the 14 ethical principles required of federal employees, a series of case studies/scenarios illustrating ethical dilemmas and resolutions, a list of key contacts for questions regarding ethics, and links to other ethics resources, policies, procedures, and documents (National Institutes of Health Ethics Office, 2009). One of the ways the agency ensures the competence of its employees, as encouraged in the eleventh principle in the code of ethics, is by the ethics training it requires of its employees and others engaged in the agency's work. These requirements are found in the ethics manual and include a mandatory ethics orientation for new employees, an annual training for all employees, and ethics training for non-employees including visiting fellows, agency volunteers, research trainees, and others who carry out the work of the agency but are not regular agency employees.

Finally, the NIH's **Public Trust Initiative** is another example of how the agency addresses the twelfth principle in the code of ethics, encouraging institutions to act in ways that build the public's trust. The Public Trust Initiative was established in 2004 by the Director of NIH with a mission "to enable the public to understand and to have full confidence in the research that NIH conducts and supports across the country and throughout the world" and the primary goal of having "the public recognize and trust the NIH in funding, conducting, and overseeing research to improve the health of the nation" (National Institutes of Health). The program spans the NIH institutes and centers and provides a centralized catalog of activities and programs across the

agency that address public's trust in the agency's work. Specifically, the Public Trust Initiative

recognizes four key roles for the program: 1) to provide the public with information regarding

NIH's research, 2) to encourage the public to participate in setting the agency's priorities, 3)

making available opportunities for the public to participate in NIH research studies, and 4)

providing the public with access to NIH-funded research results. The program recognizes that

there are many publics to which the agency is accountable and to whom its work is important

including scientists, grantees, patients, advocacy groups, health care professionals, and the public

at large. To address these multiple publics, the program maintains a web site which displays the

agency's major public trust activities and categorizes them in ways that make it easy for a variety

of audiences to access certain kinds of health and health research information including public

education campaigns, Town Hall meetings, professional education, health fairs, school-based

programs, programs for the general public such as lectures by NIH researchers on disease topics,

clinical trials openly recruiting participants, research advocacy activities, opportunities for

grantees, and programs and activities for the scientific community within and outside of NIH.

Subfinding 1.1.c: The review of publicly available documents revealed some gaps between agency ethics programs and the public health code of ethics

The review of publicly available documents revealed potential gaps for both agencies between

current programs and three of the principles in the code of ethics. Regarding the advice in

principle 3—to develop policies, programs, and priorities in a way that ensures input from

community members—the search for CDC documents did not yield information about an

agency-wide practice for addressing this. While there were numerous references to the concepts

of community input or community advisors for CDC programs or funded work, there was no

information about how those concepts are operationalized. Certain federal programs and policies

are announced and published in the Federal Register in advance of enactment in order for the general public to have an opportunity to comment on the proposed program. While the CDC receives public input in this way, the document review yielded no central, agency-wide policy, position, or mechanism for soliciting or including input from targeted communities on the work of the agency.

The public health code of ethics' principle 6 encompasses two concepts for public health institutions and is partially addressed by both CDC and NIH. The first concept—to provide communities with the information needed for decision-making—is addressed by both agencies as discussed in the previous two subfindings. The second concept—to obtain the community's consent for the implementation of policies or programs—was not explicitly addressed by either CDC or NIH based on documents reviewed for both agencies. Finally, the code's ninth principle—public health programs and policies should be implemented in a manner that most enhances the physical and social environment—was not addressed by NIH based on the documents reviewed for this study. An analysis of these potential gaps is offered in the *Discussions and Conclusions* chapter.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

The document review and key informant interviews were designed to provide insights into the study's three key questions from different perspectives. The objectives of the document review were to provide an agency-level overview of organizational components, programs, and policies that address the principles in the public health code of ethics, to illuminate any potential gaps between the code's principles and the agency's practices, and to determine targeted areas of questioning for key informant interviews with agency officials. The goal of the key informant interviews, in turn, was to develop a more detailed understanding of each agency's organization, resources, and practices devoted to addressing the principles within the public health code of ethics and to tap into any information not readily available through a search of publicly available information. This chapter contains a discussion of the findings from both study components – the document review and the key informant interviews—and are presented together by key research question.

The three key research questions for this study, designed to determine whether there is a role for the public health code of ethics in the nation's largest public health institutions, are as follows:

- Key Question 1: In the context of the 12 principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?

- Key Question 2: To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?

- Key Question 3: If benefits are identified, how can specific barriers to implementing the code of ethics be addressed to fill gaps in the agencies' current ethics programs?

Summary of Potential Gaps

Taken together, the document review and the interviews with key informants revealed that there are two principles in the code of ethics for which gaps or potential gaps were identified for CDC and three for which gaps or potential gaps were identified for the NIH. These are summarized Table 8 and are discussed in the narrative that follows.

Table 8: Potential Gaps between Code of Ethics Principles and Agency Activity

Principle from Code of Ethics (summarized) Not Fully Addressed by CDC and/or NIH	Agency with Potential Gap	Disposition
#3: ensure an opportunity for input from community members	CDC	Discrepancy: addressed by interviews, but not addressed by document review
#5: implement effective policies and programs that protect and promote health	NIH	Discrepancy: addressed by document review, but not addressed by interviews
#6: provide communities with information for decision-making and **obtain the community's consent** for program implementation	CDC and NIH	Portion of principle (underlined) not addressed by document review or by interviews
#9: enhance the physical and social environment	NIH	Not addressed by document review or interviews; falls outside of agency mission

Note: "Potential Gap" indicates that no documentary evidence was found to fully address the principle and/or: 1) no interviewee offered examples of alignment with agency work or 2) at least one interviewee stated that the principle falls outside of the agency's mission or the agency does not have policies or programs to address it.

Discussion of Results by Key Research Question

Key Question 1: In the context of the twelve principles of the public health code of ethics, what are the current practices of the CDC and the NIH, the two largest federal public health agencies?

Results from the document review and key informant interviews revealed that both agencies are addressing most of the principles in the code of ethics with their current practices, policies, and ethics activities. In some cases, there were discrepancies between the findings from the document review and the interviews as summarized in the table above. In general, these were not cases of conflicting information, but rather of information being offered or available from one collection method, but not the other. For example, while a document may be available to describe a program addressing a given principle, interviewees from the agency may not have been aware of or failed to mention anything to address the principle. In one case, only a portion of a principle was addressed by either agency.

In the case of the CDC, this study revealed potential gaps between agency practices and two code of ethics principles. First, for principle 3, while CDC officials widely agreed that the agency values and seeks input from the communities for which it designs programs, there was no publicly available evidence to support or describe how the agency does so. This is noted as a potential gap because it may be that such a policy does exist but is not offered publicly, or that CDC staff routinely incorporate this practice into their work despite not having a policy to direct the activity. Second, for principle 6, neither the document review nor the interviews provided

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evidence that the CDC has any systematic way of obtaining "community consent" for programs it implements.

The study revealed clear evidence that the remainder of the principles are addressed by CDC activities. In addition, agency officials noted that the language used in the code was directly related to the work of the CDC and is consistent with the agency's mission. In fact, the agency was instrumental in the code's development, providing funding for the effort and having several officials involved in the development of the code. In addition, several of the officials interviewed for this study regularly participate in the dissemination of the code to other agency staff and to audiences outside of the agency whom they may have occasion to address at meetings, conferences, and other venues. This leads to the conclusion that the code is well-designed for the agency and is consistent with the work of CDC.

However, results from the study of the NIH, whose programs and policies address most of the principles in the code of ethics, indicated that although the spirit of the code of ethics is consistent with the agency's mission, the way the code is written does not necessarily lend itself well to being accepted or adopted by NIH. For example, the review of documents provided evidence that the fifth principle is addressed by the agency's very mission—not only to *seek* knowledge, but to *apply* it to "enhance health, lengthen life, and reduce the burden of disease and disability" (National Institutes of Health). However, key informants did not readily recognize the agency's role in providing "information needed to implement effective policies and programs to protect health" as the fifth principle states. One possible reason for this discrepancy is that the agency is not carrying out this portion of its mission and instead, is solely focused on generating new knowledge rather than applying it. However, given the documentary evidence of numerous

programs and public health campaigns run by the agency using its research results as an evidence-base, the more likely reason for the discrepancy between the results from the document review and key informant interviews is that in general, those in leadership positions related to ethics at the agency are engaged in the establishment and enforcement of biomedical research ethics programs and the standards for ethical conduct for government employees rather than for public health programs. This notion was reinforced by one NIH official who characterized the agency's role as research-focused and not implementation-focused

Similarly, neither the document review nor the key informant interviews revealed evidence of the agency addressing the ninth principle—"Public health programs and policies should be implemented in a manner that most enhances the physical and social environment." While NIH-funded research may be applied by others to address this principle, the implementation of programs and policies to enhance the environment does not seem to fit directly with the agency's mission. Therefore, it is reasonable that this principle might not be addressed by the agency. Finally, as was the case with the CDC, this study did not reveal evidence that the NIH systematically of obtains "community consent" for programs it implements. This could be an indication that the agency does not do this or it could mean that the practice is not documented in a policy or if it is, the policy may not be publicly available. Another possibility is that the concept of community consent needs clarification from the authors of the code in order to be understood and operationalized. In any case, it is noted here as a potential gap between the agency's practice and the code of ethics principle 6.

Key Question 2: To what extent has the public health code of ethics been given specific consideration by the two largest federal public health institutions?

The results of this study showed that the key informants from the CDC had a high degree of familiarity with the code, that the agency provided support for its development in the form of funding and staff involvement, and that it is an integral part of the agency's public health ethics program. For example, it is the framework around which the agency's key public health ethics document is built (CDC Public Health Ethics Committee, 2007). The agency uses the code as a tool to help articulate its own policies and practices for public health ethics and uses it in its ethics education for staff. In this way, the code is already integrated into the agency's programs and is widely accepted as a set of principles that fits well with the CDC's mission and work. Given this high degree of familiarity, use, and alignment with mission, the agency has considered adopting the code, but ultimately declined to do so. The decision not to adopt the code appears to be less of a deliberate choice against doing so, and instead reflects a shift in agency priorities to other pressing matters. Since the deliberations about adopting the code took place, there has been a change in administration of the agency and with it a new set of priorities. As CDC officials described the situation, the matter of formally adopting the code—or continuing the discussion about doing so—simply hasn't risen to the top of the priority list. That the code is in use and is as integrated into the agency's programs as it is indicates its success as a document that can be accepted and operationalized into a large public health institution. One might assume that if the code could be accepted and infused into the programs of a large federal agency, it could also be accepted into smaller bureaucracies at the state and local levels assuming the code aligns as well with the missions of those organizations as it does with CDC's mission.

In fact, interviewees from the Public Health Leadership Society who were familiar with the code's development and dissemination noted that local and state public health agencies are a key

audience to whom they are speaking about the code of ethics and how it can be used to assist

public health professionals working through ethical dilemmas and to design and manage public

health programs in an ethical way. One of their goals is to introduce the code to a wider circle of

public health professionals through speaking engagements and workshops across the country.

The Public Health Leadership Society's dissemination goals are made challenging due to a lack

of funding. While there was funding available—from CDC and others—to develop the code,

funding has not been available to take the next steps to publicize, disseminate, and track the

code's use. Finally, the findings for this study showed no familiarity with the code among NIH

officials interviewed for this study and therefore, there has been no consideration of adopting the

code for the agency.

Key Question 3: If benefits are identified, how can specific barriers to implementing the

code of ethics be addressed to fill gaps in the agencies' current ethics programs?

In the case of the CDC, officials noted that unresolved questions about the agency's authority

and enforcement of the code pose a barrier to adopting it. In particular, the leadership group that

deliberated on the issue of adopting the code struggled to clarify what the agency's legal

responsibility would be to enforce the code if it was adopted. This circumstance reveals a

dilemma for a code that is aimed at organizations rather than individuals. In its articulation of

the rationale for the code of ethics, the Public Health Leadership Society states that "A code of

ethics thus serves as a goal to guide public health institutions and practitioners and as a standard

to which they can be held accountable" (Public Health Leadership Society, 2002). Currently, the

CDC is using the code as a part of its guidance on public health ethics by its integration into the

agency's public health ethics program and education. If the code is meant to serve as a standard

to which organizations are held accountable as the PHLS statement suggests, this question of agency authority for enforcement remains an issue to be debated and resolved prior to acceptance of the code formally.

In the course of the research for his study, it became clear that while the CDC makes a distinction between research ethics and public health ethics, the NIH does not. This led to difficulty among key informants from NIH trying to translate research ethics activities into responses to questions regarding public health ethics. Because the vast majority of NIH's work and budget are devoted to research rather than public health programs, this seems to be a reasonable approach to the design of the agency's ethics programs. In addition, NIH officials saw general alignment of the code's principles with the agency's mission; however, they questioned what value the code would bring to an agency whose resources are focused mainly on biomedical research. Finally, as with the CDC officials, NIH interviewees expressed concern regarding the agency's legal authority to establish and enforce a new set of standards for its workforce. In conclusion, the interviewees' concerns regarding the focus of the code's principles, the questionable value of the code for the agency, and questions about authority to enforce the code pose barriers that make adoption of the code at the NIH both infeasible and unnecessary.

Conclusions and Recommendations

The fact that both agencies are already addressing most of the principles within the code begs the question of what, if any, value the formal adoption of the code might have. Based on alignment with agency mission, knowledge of the code among ethics leaders, feasibility of adoption of the code, and potential value added to the agency and the field of public health, the study results lead

to the following recommendations for the CDC, NIH, and the Public Health Leadership Society, the body responsible for the creation of the code:

The CDC should formally adopt the public health code of ethics.

The study shows that the principles in the code of ethics align well with the with agency's mission and that the ethics leaders who participated in this study all had extensive knowledge of the code and, in fact, use it in the course of their work. In addition, adoption of the code is feasible for the CDC because the agency recognizes a need for a distinct public health ethics program to address the work it does and the code is already integrated into the ethics program. Finally, although there may be limited value or change to the agency by adopting the code, the value added would be largely external. The benefit to CDC adopting the code would be mainly to the field of public health. Adopting the code of ethics in a formal way would give prominence to the code and would position the CDC as a model for state and local public health institutions nationwide that may be considering adopting it.

The NIH should consider using the public health code of ethics within the workgroups that manage public health campaigns and programs.

The findings of this study indicate that NIH adopting the code has questionable value and low feasibility. The ethics leaders who participated in the study were not familiar with the code and while they found the principles generally consistent with the agency's work and mission, questioned what value adopting it would add agency-wide. The agency-wide ethics program is appropriately focused on the majority of the work there—basic biological research. However, there may be some value to introducing the code to the segment of the NIH workforce

responsible for implementing public health programs and campaigns. Using the code as a tool in the design and management of public health programs could assist in disseminating it to a wider group of public health professionals and could enhance that specific segment of the agency's work.

The Public Health Leadership Society should more clearly articulate the need the code addresses and track its use to help build an evidence base for its adoption

The study revealed that there was low recognition of the code among NIH officials whose expertise is in the field of ethics. Interviewees involved in or familiar with the development and dissemination of the code indicated that they were not aware of any organized or systematic collection of information about how the code is being used or which organizations or institutions have adopted it. If the goal is to have the code disseminated and put into use widely among public health institutions, the Public Health Leadership Society should develop a strategy for tracking and reporting on the use of the code so that others may benefit from the lessons of those who have successfully done so. This, in combination with encouraging a robust body of published work in which the code is studied, featured, and explored for benefits to the public's health would increase the code's visibility in the field and enhance the chances of it being formally adopted by organizations who could use data about the code's use to help justify formalizing it in their own organizations.

Limitations of this Research

Limitations of this research include factors that are common to the methods used to collect information for this study—document review and key informant interviews. In addition, there

are limitations unique to the topic and design of this study. As the methods chapter discusses, this study began with an initial round of document review, progressed to key informant interviews, and included a second round of review of documents suggested or provided by interviewees. The initial document review was limited to what was available publicly through each agency's web sites and other venues. While this study drew conclusions from that information about the scope of each agency's ethics programs, there are limits to how comprehensive of a picture can be drawn based on this source. For example, just because an agency has a policy or program and makes documentation about it available, it does not mean the particular code of ethics principle it addresses receives the attention it may warrant. In addition, most of the publicly available documents give no indication of how rigorously a particular program is enacted or enforced. Finally, there may be other policies or programs in place that did not appear in a search of publicly available information. These limitations were mitigated by following the document review with key informant interviews and a second phase of document review which provided an opportunity to clarify and probe on the initial document review findings and to triangulate the evidence.

The key informant interviews were subject to bias both in terms of selection and responses. First, the interview sample size is relatively small given the size of the two agencies studied. Key informants, although high level and very knowledgeable, may not be aware of all policies and programs across the entire agency. Key informants with knowledge of the development and dissemination of the code had limited knowledge about the status of any formal efforts on the part of the Public Health Leadership Society to disseminate the code and track the organizations which have adopted it. Because some representatives from the Public Health Leadership Society declined or did not respond to a request to be interviewed for this study, a gap exists in the full

picture of how the organization is disseminating the code and what its plans are for revising it or evaluating its use.

Efforts to address these limitations and potential biases included corroborating information gathered from the interviews with documentary evidence, including key informants from CDC and NIH who have expertise in the area of ethics within particular divisions of each agency as well as those who have an agency-wide perspective of ethics programs. Finally, the study has the potential for bias in responses due to the interviewees' role in the programs discussed and the researcher's role as an analyst at the GAO, the agency charged with auditing Executive Branch agencies including the CDC and NIH. This affiliation was disclosed to all invited interviewees at the initial contact which may have affected who was willing to participate in the study as well as responses provided by those who did participate.

CHAPTER 6: PLAN FOR CHANGE

The public health code of ethics is a tool that is aligned with the CDC's mission and is well-suited for formal adoption by the agency which, while perhaps not creating a great change in the agency's public health ethics practices, would serve as a model and a signal that the agency has espoused the principles and is maintaining public trust by committing to a clear set of principles by which it conducts its work on behalf of the public. The NIH has an ethics program that is appropriately geared toward research ethics and would not benefit from adopting the public health code of ethics nor would such a suggestion be feasible. However, the NIH may find some use for the public health code of ethics among the segment of the workforce that designs, manages and evaluates public health education, campaigns, and programs. In addition, the Public Health Leadership Society could use some of the information gained from the results of this study to clarify and extend the reach of the public health code of ethics.

Recommendation 1: The CDC should formally adopt the public health code of ethics.

The CDC Public Health Ethics Committee has publicly stated that "a systematic, deliberate ethical analysis" would provide an added value to the CDC's decision-making process given that the ethics problems it addresses are often complex, involve several risk factors, and involve multiple stakeholders with varied perspectives and values (CDC Public Health Ethics

Committee, 2007). Further, the Committee recognizes two main rationales for instituting a

systematic approach to ethical decision-making at the CDC: "1) to make sound decisions which

are most in agreement with public health and other societal values, and 2) to help ensure that the

decisions we make are supported by those who are affected by our actions" (CDC Public Health

Ethics Committee, 2007). The Committee refers to the public health code of ethics as a

document which articulates the key values of the field and, in fact, provided funding for the

code's development by the Public Health Leadership Society. The timing is right for the agency

to formally adopt the public health code of ethics. The CDC Public Health Ethics Committee

has recommended a more formal structure for its ethical decision-making processes, has

recognized the code as the articulation of the values of the field, and is actively working to

strengthen the agency's role in public health leadership (July/August 2008). This change is

feasible and important to the agency, the local and state public health institutions it funds, and to

field of public health. Following are suggested steps to achieve this change:

Build a Workgroup: The CDC officials interviewed for this study noted that the initial

discussions about adopting the code were rather informal and included a variety of leaders within

the agency. Since that time, the agency has undergone a re-organization and has new leadership

at the top. A gathering of the decision-makers and key advisors to the CDC Administrator into a

workgroup to study the feasibility of adopting the code would provide an organized approach to

studying the issue and arriving at recommendations for the CDC Administrator. In order to

appeal to the agency administration with a compelling rationale and plan for adopting the code,

leaders within the agency should engage the appropriate stakeholders in the process from the

beginning to ensure widespread support (Kotter, 1996)and ensure that the team is led by

efficient, knowledgeable and passionate people (Harari, 2002).

Create a vision for change and communicate it to staff and other stakeholders: Be clear

about the plan for action, the steps necessary for success, and keeping staff and other

stakeholders apprised (Harari, 2002; Kotter, 1996). The deliberations as well as the process for

adopting the code should be transparent to staff and the public. One of the benefits of having the

CDC adopt the code is external—so that it can serve as a model agency for other public health

institutions. An open debate of the barriers and benefits to adopting the code will serve those

who may be considering doing the same. The CDC has worked hard to position itself as a

federal leader in the area of public health ethics and formal adoption of the code is an important

an opportunity to solidify its role as a leader in this realm.

Be clear and concise and keep the goal in mind: Both in terms of communicating workgroup

recommendations to the decision-maker(s) in order to have the code adopted and then

communicating the change to CDC personnel, talking and teaching points must be clear, concise

and logical so that the reason for supporting adoption of the code is obvious (Harari, 2002).

Taking the message a step further (and outside of the agency), communicating the CDC decision

to adopt the code in clear, concise, and consistent language will help in the effort to disseminate

the code further into the field. While it is important to monitor the details involved with

working through the barriers to adopting the code of ethics, it is equally crucial to keep the whole

picture in mind so that the goal of systemic change is not lost (Gerzon, 2006). A proposal to

adopt the code may take time to be vetted and accepted, but each workgroup meeting,

presentation, and training on the code of ethics increases awareness and promotes interest and

discussion on the issue within the agency. These are key activities in the movement to influence

decision-makers and change culture on multiple levels (Gerzon, 2006; Kotter, 1996).

Recommendation #2: The NIH should consider using the public health code of ethics within the workgroups that manage public health campaigns and programs.

While the NIH's ethics program is appropriately focused on its primary mission—to conduct basic biologic research—the public health code of ethics may be of value to the segment of the NIH workforce that designs and implements public education materials and campaigns, namely, the communications offices throughout the agency as well as those who conduct community-based research programs. The communications offices in each institute are typically the locations from which public health campaigns and educational programs are designed, managed, and evaluated. If the NIH's Office of Communications and Public Liaison—the central coordinating body for communications activities across the agency—were to espouse the principles in the code for public health programs, it could become a useful tool for the numerous communications offices throughout the NIH. In addition, the NIH conducts several large research studies that are based in communities and are reliant upon strong community connections such as the National Children's Study and the Framingham Heart Study.

The code of ethics may offer important guidance to the researchers who are involved in creating community partnerships, designing the studies, recruiting participants, and implementing the research with these populations. Because these researchers and the communications offices deal directly with implementing programs and sharing information that could be valuable to communities making decisions about policies and programs, the code could provide a helpful framework from which to operate the ethical design and implementation of programs and partnerships. Given that the code's principles are generally aligned with the agency's mission, applying the code with a subset of the agency workforce could be a feasible approach to

integrating the principles into the work of these offices, without the need for the agency to formally adopt the code which this study showed to be infeasible and unnecessary.

The ideal strategy for disseminating the code to these sectors of the NIH workforce is a centralized approach to accepting and sharing the principles. This could be accomplished by presenting the code, with some context for why it would benefit the agency, to the NIH Director for consideration. The rationale could include the benefit to the agency of recognizing the principles as important for NIH's work within communities in a proactive way—before there is a need to justify or defend agency programs. If the Director accepts that the code is appropriate guidance for health communication and research programs, it could be shared through his regular meetings with institute and center Directors for dissemination throughout the agency. This encouragement from top leadership would serve to bring greater awareness of the code which this research showed was lacking among NIH ethics officials and could offer a set of principles focused on public health work to the segment of the agency's workforce most directly involved with research and education for communities. The code's principles could be included in recruitment materials to show potential study participants that in addition to the NIH's rigorous research ethics and protections for human subjects, the agency is sensitive to and concerned about designing and conducting research in ways that are respectful of the communities the research is designed to serve.

A second approach to sharing the code among the agency employees working directly with communities is to present it to the NIH's Office of Communications and Public Liaison—the agency's central coordinating body for all institute and center communications offices. Similarly

to the first approach, providing a rationale to the leader of that office would encourage

acceptance of the code as a tool that could offer important guidance to the agency's

communications and public health workforce. While this strategy may be somewhat easier than

accessing the NIH Director, it is somewhat less effective because the reach it would provide to

the NIH workforce is not as wide, potentially missing the researchers designing and conducting

community-based research since that work is not typically coordinated through the

communications offices. In addition, the effect of having the leader of one division—the Office

of Communications and Public Liaison—encourage the code's use is less compelling than if the

message came from the agency's top leadership.

Finally, another way the code could be operationalized informally within the agency is through

the code's inclusion in an important publication on managing health communications programs.

The National Cancer Institute—a component of the NIH— publishes a program manual entitled

"Making Health Communication Programs Work" (National Cancer Institute, 2002). The

manual includes guidance relevant to several of the code of ethics' principles. The code could be

included and infused into the fabric of the manual and in the process, could inspire more staff in

the agency (and many outside the agency who use the guide) to aspire to the principles and to

increase familiarity with the code in an important public health institution.

**Recommendation #3: The Public Health Leadership Society should expand upon its
rationale for the code of ethics and build an evidence base for its adoption.**

In its 2002 publication of the public health code of ethics, the Public Health Leadership Society

provided supporting materials including an explanation of the values and beliefs that underlie the

code, a crosswalk between the code's principles and the essential public health services, and a brief "Rationale for a Public Health Code of Ethics" (Public Health Leadership Society, 2002). The rationale describes two purposes for the code—as guidance for public health organizations and practitioners and as a set of standards to which they can be held accountable. These are two very different uses for the code with differing levels of complexity for an institution considering adopting the code as the case of the CDC illustrates. The agency currently uses the code to provide a framework for its public health ethics program and encourages its use to guide staff in how to conduct public health programs in an ethical way, thus addressing the first part of the PHLS rationale for the code (CDC Public Health Ethics Committee, 2007). This is a relatively simple way for an organization to use the code. More complex is establishing it as a standard against which the institution and staff are measured. In the case of the CDC—and one could imagine other organizations as well—using the code in this way requires a different level of commitment and resources and therefore requires a more rigorous approach to justifying the adoption of the code.

A unique feature of the code is its focus on institutions rather than individual practitioners of public health. This feature presents a challenge to those who are working to disseminate it and those who wish to adopt it. The Public Health Leadership Society can play a key role in addressing this challenge by providing a more rigorous rationale for the code. This includes enhancing its original rationale with information on how the code is being used and adopted in the field and sharing best practices for doing so. Steps to building a more robust rationale for the code include:

Track the use and adoption of the code

The Public Health Leadership Society could undertake a study of familiarity and use of the code among public health institutions such as state and local public health departments and other key audiences for the code. This could be modeled on the CDC's Public Health Ethics Survey fielded among agency staff at the time this dissertation research was in process. Such a study could provide a valuable snapshot of where the code is being used and under used according to the Society's goals. Next, the Society could use the study results to develop a strategy for outreach and dissemination, targeting the organizations it believes could benefit from but are not using the code. In addition, by publicizing the results of such a study, the organization would be providing valuable information to groups who may use the data to support use of the code in their organizations.

Share best practices for using and adopting the code

While the original publication of the code calls it a "living document," the Society does not offer a clear and active route for feedback or additional information about how the document may be revised or updated.[9] Offering a clear and public forum for feedback and stories about how the code is operationalized in some organizations could be of benefit to others seeking evidence to justify its adoption. Establishing a blog or some other repository for stories from the field could help to provide valuable lessons about how groups have handled the dilemma of whether to enforce the principles or use them as guidance rather than for accountability.

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[9] The PHLS rationale for the code sends readers to its web site to provide feedback on the code. At the time this study was undertaken, there was no active link or explanation about how to submit feedback or to whom.

Encourage the publication of a greater body of work on the impact of this and other codes of ethics on programs or outcomes.

While not strictly in the purview of the Public Health Leadership Society, the organization could play a role in encouraging public health professionals to build an evidence base for adoption (formal or informal) of the public health code of ethics. Many articles have used the code to discuss specific case studies and public health scenarios such as flu vaccines, pandemic influenza planning, genomics, and others (Melnick et al., 2005; Thomas, Irwin, Zuiker, & Millikan, 2005a; Thomas, Irwin, Zuiker, & Millikan, 2005b; Thomas et al., 2007). However, as the literature review for this study found, there is a gap in the literature on the code's adoption and use in programs. Tracking and reporting along with published peer reviewed articles would help build a base for strengthening the rationale for others to adopt the code. The Public Health Leadership Society has made an important contribution to the field in its creation of the public health code of ethics. It could increase the code's use and utility to the practice of public health by taking the next step to enhance the rationale for its adoption which could in turn facilitate greater number of organizations in their efforts to adopt the code formally.

In conclusion, there is a role for the public health code of ethics in the federal workforce. The CDC should adopt the code for use agency-wide and the NIH should consider using the code with the segment of its employees doing direct public health outreach. The Public Health Leadership Society should take a more active role in articulating the need for the code and engage in activities that will facilitate a wider use of the code.

Appendix A

Fact Sheet for Adult Participants in a Research Study
University of North Carolina-Chapel Hill

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IRB Study #09-1834
Consent Form Version Date: May 2009
Title of Study: Applying the Public Health Code of Ethics to the Federal Workforce
Principal Investigator: Jill K. Center, MPH
UNC-Chapel Hill Department: School of Public Health, Department of Health Policy and Management
UNC-Chapel Hill Phone number: 919/966-7364
Faculty Advisor: Edward Brooks, DrPH, MBA
Study Contact telephone number: 202/544-8112
Study Contact email: jcenter@email.unc.edu

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What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about how the public health code of ethics relates to the ethics programs already in place at The National Institutes of Health and the Centers for Disease Control and Prevention.

You are being asked to be in the study because you have professional responsibilities related to training, implementation, or oversight of ethics programs, policies, and procedures within your agency or office.

How many people will be interviewed for this study?

If you decide to be interviewed for this study, you will be one of approximately 15-20 people interviewed for this research study.

How long will your part in this study last?

If you decide to be interviewed for this study, you will be asked to meet in-person or by telephone for a 45-60 minute interview. If you agree, you may also be contacted by e-mail or telephone to address follow up questions or clarifications if needed.

What will happen if you take part in the study?

Participation in interviews for this study will involve the following steps:

- Read this fact sheet and the information enclosed to determine your interest in participating in this study
- Contact the researcher listed on the first page of this form with any questions or concerns regarding your participation
- Schedule a time to participate in a 45-60 minute interview (interviews may be conducted in-person or over the telephone)
- Read the enclosed 12 page code of ethics entitled *Principles of the Ethical Practice of Public Health* before the interview and consider whether or how it aligns with your agency's/organization's mission
- Participate in a 45-60 minute interview in-person or over the telephone
- Address follow up questions or clarifications if needed after the interview

What are the possible benefits from being in this study?

You may benefit from participation in this study by discovering ways the public health code of ethics could enhance the current ethics programs and policies in place in the agency where you work. This research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There are no known or expected risks to participating in this study.

How will your privacy be protected?

The researcher listed on the first page of this form is the only person who will have access to information that links individual participants to the responses from their interviews.

- Participants will be asked for permission before being identified in any report or publication about this study.
- Records of the interview will be stored electronically in password protected files.

- At the time of the interview, participants will be asked for permission to record the interview for transcription. If an interview is recorded, a transcript will be made and the audiotape will be destroyed.
- Any hardcopy information linked to an individual's responses to interview questions will be stored in a locked file cabinet.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Will you receive anything for being in this study?

You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?

Other than your time, there will be no costs for participating in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researcher listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research with human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the Institutional Review Board at 919/966-3113 or by email to IRB_subjects@unc.edu.

Key Informant Interview Tool A: Question Set for Officials at the National Institutes of Health and the Centers for Disease Control and Prevention

Welcome

Thank you for agreeing to participate in this interview to discuss the public health code of ethics. I am Jill Center, a student in the UNC Doctor of Public Health Program. I am also a Health Policy Analyst at the U.S. Government Accountability Office. As I indicated in the introductory letter, the information I collect as a part of this study is for my dissertation research and is not related to any active GAO engagement.[10] I will not share any details from this interview with colleagues at GAO. I may publish portions of the dissertation, in which case the findings would become publicly available.

In order to fully capture your responses today, I would like to record our conversation. Do I have your permission to do so? [If yes]: If you would like to have me stop the recording at any point in our conversation, please let me know and I will stop the recording.

Introduction

Leaders in public health have undertaken an effort to further "professionalize" the field by identifying a common set of competencies for the public health workforce, marketing a national credentialing examination to test for mastery of several core competencies, and proposing that public health professionals be certified to engage in certain core activities. Another aspect of this movement is the development of a code of ethics for public health institutions.

In 2002, the Public Health Leadership Society published the Principles of the Ethical Practice of Public Health (code of ethics), which includes the twelve principles that make up the code of ethics. Although it was adopted by the American Public Health Association and has been endorsed by several public health organizations, there appears to be little organized effort to disseminate the code or to integrate it into the public health workforce.

In order to learn about whether the code of ethics would be a useful tool for the two largest public health agencies—NIH and CDC— I am conducting a series of interviews with ethics professionals and other officials at the two agencies. Thank you for agreeing to participate in this interview to discuss your opinions about the public health code of ethics and to share

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[10] Key informants received an introductory letter describing the research objectives, my affiliation with GAO, and a copy of the public health code of ethics. The letter requested that participants read the code of ethics in advance of the interview.

information about your agency and how the code of ethics might fit into its ethics program.

Interview Questions

1. Please describe your role in the agency's ethics program.

2. Had you seen or heard about the public health code of ethics before I sent it to you?

3. **To what extent does the public health code of ethics align with your agency's mission?**

4. **For the elements you identified that align with the agency's mission, to what extent do current agency policies and practice address these? [If participant does not mention gaps revealed by my analysis of publicly available documents, probe on those items.]**

5. **How does your agency train employees in the ethics policies and what support is available when an ethical question arises?**
   a. **How does your agency keep them informed of changes to the policies?**
   b. **Are there documents you could share pertaining to these practices?**

6. **What is the process for making a change to your agency's ethics programs?**
   a. **Who are the decision-makers?**
   b. **Are there documents you could share pertaining to these procedures?**

7. **Please describe any barriers to changing your agency's ethics programs.**

8. **If you identified an element of the code of ethics that you thought should be adopted by the agency, what would be the steps you would need to take to have the idea considered?**

9. [If applicable]: Of the elements we've discussed that align with your agency but are not currently reflected in its policies, which do you think are the most important?

10. Are there any additional thoughts or opinions about the public health code of ethics that you would like to share?

11. Are there others at NIH/CDC that you would recommend I speak with about this topic? May I contact you again with follow up questions or for clarifications?

Conclusion
Thank you for your time today to discuss the public health code of ethics. The information and insights you shared will be valuable to my study. May I use your name and title in the final report, or would you prefer that I keep all or part of that information anonymous? If you are interested, I would be happy to share the results of my research when the final report has been approved and accepted by UNC (expected 2010).

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