• Managed care plans could adopt the project and encourage their enrollees to have themselves assessed for risk and alter their lifestyles if the risk warrants;

• Colleges and universities could conduct detection events for their student populations;

• Area agencies on aging could form a component of a statewide program.

Where a statewide program is not in place, partnering organizations such as these could proceed on their own.

Availability of Funds

There are no Federal funds available for these partnerships.

Content of Request for Partnership

Each request for partnership should contain a description of: (1) The entity or organization; (2) its proposed involvement in the Department's diabetes detection initiative; and (3) resources or services the partnering organization would like to offer.

Evaluation Criteria

Partners will be selected by the Office of Disease Prevention and Health Promotion using the following criteria:

(1) Requester's qualifications and capability to contribute to the partnership;

(2) Requester's creativity for contributing to the diabetes detection initiative.

Dated: March 25, 2003.

Elizabeth Majestic,

Acting Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), Department of Health and Human Services.

[FR Doc. 03–7692 Filed 3–28–03; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 02N–0475]

Draft ''Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

AGENCY: Office of the Secretary, Office of Public Health and Science, HHS.

ACTION: Notice.

SUMMARY: The Office of Public Health and Science, Department of Health and Human Services (HHS) is soliciting public comment on a draft guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled ''Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection.'' This draft guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the Food and Drug Administration.

DATES: Submit written or electronic comments on the draft guidance on or before 4:30 p.m. on May 30, 2003. Comments on HHS guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Docket Number 02N–0475, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* All comments submitted should be identified with the docket number found in brackets in the heading of this notice. Comments received may be viewed on the Food and Drug Administration (FDA) Web site at *http://www.fda.gov/ohrms/dockets/default.htm* or may be seen in the FDA Docket Management Branch at 5630 Fishers Lane, Room 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

Submit requests for single copies of the draft guidance document to the address identified below for further information. Requests may be made by mail or e-mail. Persons with access to the Internet also may obtain the document at *http://www.fda.gov/ohrms/dockets/GUIDANCES/DGUIDES.HTM.*

FOR FURTHER INFORMATION CONTACT: Glen Drew, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (301) 402–4994, facsimile (301) 402–2071; e-mail *gdrew@osophs.dhhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

OPHS is seeking comments on the HHS draft guidance for IRBs, investigators, and research institutions, entitled ''Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection.'' In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and financial conflicts of interest on August 15–16, 2000. A draft interim guidance document, ''Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection,'' based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001. This document will replace that draft interim guidance.

The draft guidance recommends consideration of approaches and methods for dealing with issues of financial interests under the HHS human research subject protections regulations, 45 CFR part 46 and 21 CFR parts 50 and 56. The draft guidance expressly does not address regulatory requirements designed to enhance data integrity and objectivity in research found in 42 CFR part 50, subpart F, 45 CFR part 94, and 21 CFR part 54.

The draft guidance recommends that, in particular, IRBs, institutions engaged in research, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. The guidance poses general considerations in evaluating financial relationships and their possible effects on human subjects. More detailed points for consideration are also offered for institutions, IRBs, and investigators.

II. Request for Comments

OPHS is distributing this draft guidance document for public comment. The Secretary is interested not only in reactions to the Guidance in general, and specifically the Points for Consideration, but also wishes to solicit views and ideas as to how to best assess any impacts of this guidance, as well as related non-Federal recommendations on enhancing the protection of human subjects. HHS guidance on consideration of financial interests in human subjects research will be issued after the public comments have been considered.

III. Draft Guidance Document

Department of Health and Human Services

Draft Guidance Document

March 31, 2003.

Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection [1]

This document will replace the ''HHS Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection'' Dated January 10, 2001.

I. Introduction

A. Purpose

In this draft guidance document the Department of Health and Human Services (HHS, or the Department) raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects [2] and if so, what actions could be considered to protect those subjects. This draft guidance applies to human subjects research conducted or supported by HHS or regulated by the Food and Drug Administration (FDA). This document addresses only requirements for human subject protection (45 CFR part 46, 21 CFR parts 50, 56) [3] This document is nonbinding and does not change any existing regulations or requirements, and does not impose any new requirements.

Institutions and individuals involved in human research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property rights. A financial interest related to a research study may be a conflicting financial interest if it will, or may be reasonably expected to, create a bias stemming from that financial interest. Furthermore, the Department recognizes that some financial interests in research may potentially or actually affect the rights and welfare of subjects, and this document provides some possible approaches to consider in assuring that subjects are adequately protected. Institutional review boards (IRBs), institutions, and investigators engaged in human subjects research each have appropriate roles in ensuring that financial interests do not compromise the protection of research subjects.

B. Target Audiences

The principal target audiences include institutions engaged in human subjects research and their officials, investigators, IRB members and staffs, and other interested parties.

C. Underlying Princinles

The regulations protecting human research subjects are based on the ethical principles described in the Belmont report: [4] respect for persons, beneficence, and justice. Financial relationships in human research should not compromise any of these principles. Openness and honesty are indicators of respect for persons, characteristics that promote ethical research and can only strengthen the research process.

D. Basis for This Document

The HHS human subject protection regulations (45 CFR part 46) require that institutions performing HHS conducted or supported non-exempt research involving human subjects have the research reviewed by an IRB whose goal is to help ensure that the rights and welfare of human subjects are protected. The comparable FDA regulations (21 CFR parts 50 and 56) require that FDA regulated research involving human subjects is reviewed by such an IRB. Under these regulations, IRBs are responsible for, among other things, determining that:

- Risks to subjects are minimized (45 CFR 46.111(a)(1), 21 CFR 56.111(a)(1));
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects (45 CFR 46.111(a)(2), 21 CFR 56.111(a)(2));
- Selection of subjects is equitable (45 CFR 46.111(a)(3), 21 CFR 56.11 1(a)(3));
- Informed consent will be sought from each prospective subject (45 CFR 46.111(a)(4), 21 CFR 56.111(a)(4)); and,
- The possibility of coercion or undue influence is minimized (45 CFR 46.116, 21 CFR 50.20).

In addition the IRB may

- Require that additional information be given to subjects ''when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects'' (45 CFR 46.109(b), 21 CFR 56.109(b)).

For HHS conducted or supported research, the funding agency may impose additional conditions as necessary for the protection of human subjects (45 CFR 46.124).

IRBs are also responsible for ensuring that members who review research have no conflicting interest. 45 CFR 46.107(e) directly addresses conflicts of interest

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[1] This document is intended to provide guidance. It does not create or confer rights for or on any person and does not operate to bind HHS, including FDA, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

[2] Under the Public Health Service Act and other applicable law, HHS has authority to regulate institutions engaged in HHS conducted or supported research involving human subjects. For a description of what is meant by institutions engaged in research see the Office for Human Research Protections (OHRP) engagement policy at *http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm.* Under the Federal Food, Drug, and Cosmetic Act, FDA has the authority to regulate Institutional Review Boards (IRBs) and investigators involved in the review or conduct of FDA-regulated research.

[3] This document does not address HHS Public Health Service regulatory requirements that cover institutional management of the financial interests of individual investigators who conduct PHS supported research. (42 CFR part 50, subpart F, and 45 CFR part 94). This document also does not address FDA regulatory requirements that place responsibilities on sponsors to disclose certain financial interests of investigators to FDA in marketing applications (21 CFR part 54). Guidelines interpreting the application of the PHS regulations to research conducted or supported by NIH that involve human subjects are available at *http://grants.nihgov/grants/guide/notice-files/NOT-OD–00–040.html.* Guidance interpreting the provisions of the FDA regulations appears at *http://www.fda.gov/oc/guidance/financialdis.html.*

The PHS regulations require grantee institutions and contractors to designate one or more persons to review investigators' financial disclosure statement describing their significant financial interests and ensure that conflicting financial interests are managed, reduced, or eliminated before expenditure of funds (42 CFR 50.604(b), 45 CFR 94.4(b)). The PHS threshold for significant financial interest is $10,000 per year income or equity interests over $10,000 and 5 percent ownership in a company (42 CFR 50.603, 45 CFR 94.3). The regulations give several examples of methods for managing investigators' financial conflicts of interest (42 CFR 50.605(a), 54 CFR 94.5(a)).

Sponsors are required to disclose certain financial interests of clinical investigators to FDA in marketing approval applications under the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 CFR part 54). FDA regulations at 21 CFR part 54 address requirements for the disclosure of certain financial interests held by clinical investigators. The purpose of these regulations is to provide additional information to allow FDA to assess the reliability of the clinical data (21 CFR 54.1). The FDA regulations require sponsors seeking marketing approval for products to certify that investigators do not have certain financial interests, or to disclose those interests to FDA (21 CFR 54.4). These regulations require sponsors to report (1) financial arrangements between the sponsor and the investigator whereby the value of the investigator's compensation could be influenced by the outcome of the trial, (2) any proprietary interest in the product studied held by the investigator; (3) significant payments of other sorts over $25,000 beyond costs of the study; or(4) any significant equity interest in the sponsor of a covered study (21 CFR 54.4).

Note that when the PHS regulations were promulgated, the National Science Foundation (NSF) Investigator Financial Disclosure Policy was revised to match closely the PHS regulations. The NSF conflict of interest policy appears at *http://www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5.*

[4] *http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm.*

by requiring that ''no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.'' FDA regulations include identical language at 21 CFR 56.107(e).

Concerns have grown that financial conflicts of interest in research, derived from financial relationships and the financial interests they create, may affect the rights and welfare of human research subjects. Financial interests are not prohibited, and not all financial interests cause conflicts of interest or harm to human subjects. HHS recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships. However, to the extent financial interests may affect the rights and welfare of human subjects in research, IRBs, institutions, and investigators need to consider what actions regarding financial interests may be necessary to protect those subjects.

In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and financial conflict of interest on August 15–16, 2000. A draft interim guidance document, ''Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection,'' based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001.[5] This document replaces that draft interim guidance. The Department notes that other organizations have also addressed financial interests in human research via reports, guidance and recommendations.[6] Many of these contain strong and sound ideas for actions to deal with potential financial conflicts of interest on the part of institutions, investigators and IRBs.

II. Guidance for Institutions, IRBs and Investigators

A. General Approaches to Address Financial Relationships and Interests in Research Involving Human Subjects

The Department recommends that in particular, IRBs, institutions engaged in research, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. These entities may elect to include the following questions in their deliberations:

- What financial relationships and resulting financial interests cause potential or actual conflicts?
- At what levels could those interests cause potential or actual conflicts?
- What procedures would be helpful, including those to

—collect and evaluate information regarding financial relationships related to research,

—determine whether those relationships potentially cause a conflict,

—determine what actions are necessary to protect human subjects and ensure that those actions are taken?

- Who should be educated regarding financial conflict of interest issues and policies?
- What entity or entities would examine individual and/or institutional financial relationships and interests?

B. Points for Consideration

Financial interests may be managed by eliminating them or mitigating their potentially negative impact. A variety of methods or combinations of methods may be effective. Some methods may be implemented by institutions engaged in the conduct of research, and some methods may be implemented by IRBs. Some of those may apply before research begins, and some may apply during the conduct of the research.

In establishing and implementing methods to protect the rights and welfare of human subjects from conflicts of interest created by financial relationships of parties involved in research, the Department recommends that IRBs, institutions engaged in research, and investigators consider the questions below. Additional questions may be appropriate. The Department's intent is not to be exhaustive, but to suggest ways to examine the issues so that appropriate actions can be taken for protection of the rights and welfare of human research subjects.

- Does the research involve financial relationships that could create conflicts of interest?

—How is the research supported or financed?

—Where and by whom was the study designed?

—Where and by whom will the resulting data be analyzed?

- What interests are created by the financial relationships involved in the situation?

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[5] *http://ohrp.osophs.dhhs.gov/humansubiects/finreltn/finguid.htm.*

[6] Recent Federal and Private Sector Activities: In addition to the HHS initiative, several Federal organizations have examined the issues related to financial relationships in human subjects research:

- The National Bioethics Advisory Commission (NBAC), in a comprehensive examination of the ''Ethical and Policy Issues in Research Involving Human Participants,'' in Chapter 3 recommended development of federal, institutional, and sponsor policies and guidance to ensure that research subjects' rights and welfare are protected from the effects of conflicts of interest (*http://www.georgetown.edu/research/nbcbl/nbac/human/overvoll.pdf*).
- The HHS Office of the Inspector Genera] (OIG) has issued a series of reports examining regulation and activities of IRBs. A June 2000 OIG report addressed recruitment practices and found that about one-quarter of the surveyed IRBs consider financial arrangements with sponsors of research as part of their protocol review. (*http://oig.hhs.gov/oei/reports/oei–01–97–00195.pdf*).
- The National Human Research Protections Advisory Committee (NHRPC) offered advice to HHS regarding the content and finalization of the HHS Draft Interim Guidance in August, 2001 (*http://ohrp.osophs.dhhs.gov/nhrpac/documents/augo1a.pdf*).
- In December 2001, the General Accounting Office released report 02–89 ''Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest.'' The report recommended that the Secretary of Health and Human Services develop specific guidance or regulations concerning institutional financial conflicts of interest (*http://www.gao.gov/*).
- A number of nongovernmental organizations recently have addressed financial interests in reports and issued new or updated policies or guidelines of varying scope and specificity, including the Association of American Universities, October 2001 (*http://www.aau.edu/research/COI.01.pdf*), the Association of American Medical Colleges, December 2001 and October 2002 (*http://www.aamc.org/members/coitf/firstreport.pdf* and *http://www.aamc.org/members/coitf/2002coireport.pdf*), the International Committee of Medical Journal Editors October 2001 (*http://www.icmje.org/sponsor.htm*), the American Medical Association, January 2002 (*http://jama.ama–assn.org/issues/v287n1/abs/jsc10070.html*), the American Society of Gene Therapy, April 2000 (*http://www.asgt.org/policy/index.html*), and the Institute of Medicine, October 2002,report ''Responsible Research: A Systems Approach to Protecting Research Participants'' (*http://www.nap.edu/books/0309084881/html/*)

Two accrediting bodies for human subject protection programs have included elements addressing individual and institutional conflicts of interest in their accreditation evaluations, the *Association for the Accreditation of Human Research Protection Programs* (*http://www.aahrpp.org/images/Evaluation_Instrument_1.pdf*), and the National Committee for Quality Assurance, (*http://www.ncqa.org/Programs/QSG/VAHRPAP/vahrpapfindstds.pdf*).

Internationally, the World Medical Association's revision in 2000 of the Declaration of Helsinki, (*http://www.wma.net/e/policv/17–c_e.html*) principle 22, includes ''sources of funding'' among the items of information to be provided to subjects. A number of individual institutions also have developed policies for their own situations, as noted in the NIH Guide Notice issued in June 2000 (*http://grants.nih.grants/guide/notice-files/NOT-OD–00–040.html*). Some of these policies involve conflicts of interest management methods and address institutional financial interests as well as individual interests.

—Do individuals or institutions receive any compensation that may be affected by the study outcome?
—Do individuals or institutions involved in the research:
+have any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?
+have an equity interest in the research sponsor and is it a publicly held company or non-publicly held company?
+receive significant payments of other sorts? (*e.g.* grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria)
+receive payment per participant or incentive payments, and are those payments within the norm?

• Given the financial relationships involved, is the institution an appropriate site for the research?

• How should financial relationships that potentially create a conflict of interest be managed?

Would the rights and welfare of human subjects be better protected by any or a combination of the following:

+reduction of the financial interest?
+disclosure of the financial interest to prospective subjects?
+separation of responsibilities for financial decisions and research decisions?
+additional oversight or monitoring of the research?
+an independent data and safety monitoring committee or similar monitoring body?
+modification of role(s) of particular research staff or changes in location for certain research activities, *e.g.,* a change of the person who seeks consent, or a change of investigator?
+elimination of the financial interest?

C. Specific Issues for Consideration Regarding

1. Institutions

The Department recommends that institutions engaged in federally conducted or supported human subjects research consider the following actions or other actions regarding financial conflicts of interest:

• Separate responsibilities for financial decisions and research decisions.

• Establish conflict of interest committees (COICs) [7] or identify other bodies or persons to deal with individuals' financial interests in research or verify their absence.

• Extend the responsibility of the COIC to address institutional financial interests in research or establish a separate COIC to address institutional financial interests in research.

• Establish criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.

• Establish clear channels of communication between COICs and IRBs.

• Establish policies on providing information, recommendations, or findings from COIC deliberations to IRBs.

• Establish measures to foster the independence of IRBs and COICs.

• Include IRB members and staff and appropriate officials of the institution, along with investigators, among the individuals who report financial interests to COICs.

• Establish procedures for disclosure of institutional financial relationships to COICs.

• Provide training to appropriate individuals regarding financial interest requirements.

• Use independent organizations to hold or administer the institution's financial interest.

• Include individuals from outside the institution in the review and oversight of financial interests in research.

• Establish policies regarding the types of relationships that may be held by parties involved in the research and circumstances under which those financial relationships and interests may be held.

2. IRB Operations

The Department recommends that institutions engaged in human subjects research and IRBs that review HHS conducted or supported human subjects research or FDA regulated human subjects research consider establishing policies and procedures addressing IRB member potential and actual conflicts of interest as part of overall IRB policies and procedures. These might include:

• Reminding members of conflict of interest policies at the start of each meeting.

• Polling members to verify that no conflicts of interest exist regarding any protocols to be considered during the meeting.

• Recording the polling results in the meeting minutes.

• Recording in the meeting minutes verification for each protocol that any conflicted members did not participate in discussion or vote on protocols involving their conflict of interest, except to provide information as requested by the IRB (45 CFR 46.107(e), 21 CFR 56.107(e)).

• Developing educational materials about the regulations' requirements for IRE members.

3. IRB Review

The Department recommends that IRBs reviewing HHS conducted or supported human subjects research or FDA regulated human subjects research consider the following actions, or other actions related to conduct or oversight of research, based on particular situations:

• Determine whether methods being considered or used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.

• Determine when an IRB needs additional information to decide whether the financial interests of parties involved in research could affect the rights and welfare of subjects as well as mechanisms for obtaining the additional information.

• Determine what actions are necessary to minimize risks to subjects.

• Determine the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

4. Investigators

The Department recommends that investigators consider the potential effect that a financial relationship of any kind might have on a clinical trial, including interactions with research subjects, and whether to take any of the following actions:

• Including information in the consent document, such as
—the source of funding and funding arrangements for the conduct and review of research, or
—information about a financial arrangement of an institution or an investigator and how it is being managed.

• Using special measures to modify the consent process when a potential or actual financial conflict exists, such as
—having a non-biased third party obtain consent, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.

[7] The acronym COIC will be used to represent the body or person(s) designated to review financial interests.

• Considering independent monitoring of the research, *e.g.*, using a data and safety monitoring committee.

Dated: March 21, 2003.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 03–7691 Filed 3–28–03; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day–03–54]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506 (c) (2) (A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Emergency Epidemic Investigations (0920–0010)—Extension—(Epidemiology Program Office, EPO)—One of the objectives of CDC's epidemic services is to provide for the prevention and control of epidemics and protect the population from public health crises such as man made or natural biological disasters and chemical emergencies. This is carried out, in part, by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect the public's health. When state, local, or foreign health authorities request help in controlling an epidemic or solving other health problems, CDC dispatches skilled epidemiologists from the Epidemic Intelligence Service (EIS) to investigate and resolve the problem. Resolving public health problems rapidly ensures costs effective health care and enhances health promotion and disease prevention. Annually, the EIS Program coordinates 400 Epidemic Assistance Investigations (Epi-Aids) and state-based field investigations. Epidemics are prevented and controlled by mobilizing and deploying CDC staff, primarily EIS officers to respond rapidly to disease outbreaks and disaster situations. At the request of public health officials—at the state, national, or international level-CDC provides assistance by participating in epidemiologic field investigations.

The purpose of the Emergency Epidemic Investigation surveillance is to collect data on the conditions surrounding and preceding the onset of a problem. The data must be collected in a timely fashion so that information can be used to develop prevention and control techniques, to interrupt disease transmission and to help identify the cause of an outbreak. Since the events necessitating the collections of information are of an emergency nature, most data collection is done by direct interview or written questionnaire and are one-time efforts related to a specific outbreak or circumstance. If during the emergency investigation, the need for further study is recognized, a project is designed and separate OMB clearance is required. Interviews are conducted to be as unobtrusive as possible and only the minimal information necessary is collected. The Emergency Epidemic Investigations is the principal source of data on outbreaks of infectious and noninfectious diseases, injuries, nutrition, environmental health and occupational problems.

Each investigation does contribute to the general knowledge about a particular type of problem or emergency, so that data collections are designed taking into account similar situations in the past. Some questionnaire have been standardized, such as investigations of outbreaks aboard aircraft or cruise vessels.

The Emergency Epidemic Investigations provides a range of data on the characteristics of outbreaks and those affected by them. Data collected include demographic characteristics, exposure to the causative agent(s), transmission patterns and severity of the outbreak on the affected population. These data, together with trend data, may be used to monitor the effects of change in the health care system, planning of health services, improving the availability of medical services and assessing the health status of the population.

Users of the Emergency Epidemic Investigations data include, but are not limited to EIS Officers in investigating the patterns of disease or injury, investigating the level of risky behaviors, identifying the causative agent and identifying the transmission of the condition and the impact of interventions.

It is difficult to predict the number of epidemic investigations which might occur in any given year. The previous three years' experience shows an annualized burden of 2,304 hours and respondent total of 10,150. Therefore, the request is for an estimated annual burden of 3,000 hours. This represents an estimated 12,000 respondents annually at 15/60 hours per response. There are no costs to respondents other than time.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Total Respondents	12,000	1	15/60	3,000