# Public Health Service Agencies

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Evaluation Systems for HIV/AIDS Prevention Programs

We will examine the evaluation systems used by the Centers for Disease Control and Prevention (CDC) to monitor compliance with grant requirements and measure the effectiveness of the HIV/AIDS youth education/prevention programs that it funds. Half of all new HIV infections in the United States occur in people under age 25, and CDC reports that approximately 40,000 persons are infected each year. Through cooperative efforts with national organizations and the States, CDC supports training for more than 180,000 teachers annually on administering HIV youth education programs in schools. In each of the past 5 years, these programs received approximately $46 million. The average grant received by each State is about $217,000.

OEI; 00-00-00000

Oversight of National Academy of Sciences Study

At the request of the Senate Committee on Small Business, we will evaluate whether (1) the National Institute of Occupational Safety and Health has exercised appropriate oversight of a National Academy of Sciences (NAS) study of musculoskeletal disorders in the workplace and (2) expenditures of appropriated funds have been consistent with the legislative language authorizing their use. The Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 provided $890,000 to the Office of the Secretary for an NAS contract to “conduct a study of available scientific literature examining the cause-and-effect relationship between repetitive tasks in the workplace and musculoskeletal disorders . . . ."

OAS; W-00-00-50003; A-15-00-30002

Controls Over Program Budgeting and Accounting

We will determine whether CDC has established internal and management controls adequate to ensure that (1) budgets established for individual programs reflect any guidance provided by the Congress and the Department; (2) costs charged to those programs are based on the actual efforts of employees and use of other resources; and (3) financial reports provided to the Congress and the Department regarding the nature and extent of costs for specific programs and activities are timely, complete, and accurate.
Building on information obtained during our recent review of costs charged to the Chronic Fatigue Syndrome program, we will focus on programs for which CDC has received specific budgetary guidance or for which CDC officials have provided the Congress and the Department with detailed data related to program costs.

OAS; W-00-01-50003; A-04-01-00000

Followup on Chronic Fatigue Syndrome Management Issues

We will assess the effectiveness of CDC’s actions in response to our May 1999 review of the Chronic Fatigue Syndrome program. The CDC agreed to implement a number of recommended actions designed to enhance its controls over budgeting and accounting functions for programs operating within its various centers, institutes, and offices. We will determine whether CDC’s actions are adequate to prevent any recurrence of the problems identified during our prior review and, if appropriate, present additional recommendations to further enhance control systems.

OAS; W-00-01-50003; A-04-01-00000

Controls Over Physical Security

We will follow up on actions taken by CDC to improve controls over physical security at headquarters facilities in Atlanta, Georgia. In response to an OIG audit report, CDC agreed in July 1996 to specific actions to improve controls at these facilities. In FY 1997 appropriations, the Congress provided CDC with $23 million to begin security improvements. We will determine whether our previous recommendations have been implemented and whether additional safeguards are necessary.

OAS; W-00-01-50003; A-04-01-00000

FOOD AND DRUG ADMINISTRATION

Retail Food Safety

We will examine the effectiveness of the Food and Drug Administration’s (FDA) food safety activities in the retail food business. Nearly half of American food dollars are spent on foods sold at over a million retail food outlets and one and a half million vending operations. In accordance with the Public Health Service Act, retail establishments are inspected by States under Federal-State cooperative programs; FDA’s primary role is to assist and advise State and local governments in carrying out the programs. Since 1978, FDA has issued a voluntary
“Food Code” that provides technical assistance to retail establishments and State and local monitors. The code has been adopted by 32 States. To monitor retail establishments and their voluntary compliance with the Food Code and other retail food safety guidance, FDA relies on more than 3,000 State and local agencies. We will examine the effectiveness of these cooperative relationships.

OEI; 00-00-0000

Oversight of National Conferences

We will examine FDA’s role in the National Conferences that oversee the Federal-State cooperative programs for food safety. Under these programs, States inspect shellfish, milk products, and retail establishments, and FDA’s primary role is to assist and advise State and local governments. Policy and standards for the cooperative programs are overseen by three distinct National Conferences, each made up of industry, Federal, State, and local regulators. We will examine FDA’s authorities to oversee the conferences and its role in setting standards for the cooperative programs to ensure the safety and quality of shellfish, milk, and retail products. The CDC recently estimated that food-borne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the United States and that the annual cost of foodborne illness amounted to $7.7 billion to $23 billion.

OEI; 00-00-0000

Biennial Inspection Requirement

We will assess whether FDA is meeting its statutory requirement to inspect drug and device manufacturers every 2 years. Previous OIG work indicated that FDA is not doing so, even though such inspections are critical to ensure that firms comply with good manufacturing practices. If FDA is unable to meet this legal requirement, we will examine the agency’s efforts to develop alternative methods to assess compliance with good manufacturing practices.

OAS; W-00-01-50004; A-15-01-00000

Expected Issue Date: FY 2002

Effectiveness of MedWatch

We will evaluate the effectiveness of MedWatch, FDA's medical products safety reporting program. The FDA is responsible for ensuring the safety and efficacy of all regulated, marketed medical products, including drugs, biologics, medical and radiation-emitting devices, and special nutritional products. Created in 1996, MedWatch was designed to (1) educate health professionals about the importance of monitoring for and reporting adverse reactions and other problems to FDA and/or the manufacturer, (2) enhance the effectiveness of
postmarketing surveillance of medical products, and (3) ensure that safety and labeling changes are rapidly communicated to the medical community, thereby improving patient care.

OEI; 00-00-00000

Expected Issue Date: FY 2002

Adverse Event Reporting System

We will assess the capability of the Adverse Event Reporting System (AERS) to support postmarketing surveillance of drugs and adverse drug experiences, one of FDA’s chief responsibilities. In 1997, FDA began replacing the 1960's-designed Spontaneous Reporting System with AERS, a new computerized database system.

OAS; W-00-00-50004; A-15-00-30001

Orphan Products

We will evaluate the impact of the Orphan Drug Act of 1983 on the development of “orphan” products. An orphan disease is one that affects fewer than 200,000 Americans per year; currently, approximately 5,000 orphan diseases affect 20 million individuals. The Orphan Drug Act was intended to stimulate the private sector’s development and marketing of treatments for these diseases, thereby improving patient access to new therapies.

OEI; 09-00-00380

Sponsors’ Oversight of Implementation of Clinical Trials

We will examine how sponsors of clinical trials monitor the implementation of the trials by clinical investigators. Sponsors are normally drug, device, or biologic manufacturers that plan to submit an application for FDA approval. They are responsible for ensuring that clinical trials are conducted in accordance with FDA regulations but may delegate any or all of these responsibilities to a contract research organization. The FDA holds these organizations accountable for any delegated responsibilities. Our review will look at such issues as how often sponsors or contract research organizations visit clinical investigators, whether the results of such visits are shared with FDA, and how often sponsors or contract research organizations discontinue clinical investigators’ participation in clinical trials.

OEI; 00-00-00000
Accreditation and Quality Oversight of Mammography Facilities

We will review the accreditation and regulatory oversight process for mammography facilities since the enactment of the Mammography Quality Standards Act of 1992. The act, which gave enforcement authority to FDA, includes requirements that all mammography facilities undergo periodic review of their clinical images; have an annual survey by a medical physicist; and meet federally developed quality standards for personnel qualifications, recordkeeping, and reporting. The law was reauthorized in 1998, extending it to 2002.

OEI; 00-00-00000

Followup on Blood Safety Issues

This review will examine FDA’s efforts to improve its oversight of the safety of the Nation’s blood supply. Our work will focus on problems the OIG previously identified regarding the blood error and accident reporting process, the blood recall process, and the inspection process for plasma fractionators. Our objective will be to determine if FDA has implemented the specific recommendations made in earlier OIG reports.

OAS; W-00-01-50004; A-03-01-00000

Bioterrorism Research Program

We will assess FDA's actions to implement its bioterrorism research program. The FDA has included $11.5 million in its FY 2001 budget request to develop vaccines, diagnostic products, and rapid detection methods to counter bioterrorism threats. This review will build on an earlier assessment, conducted at the request of the Subcommittee on Oversight and Investigations, House Committee on Commerce, of FDA’s FY 2000 activity in bioterrorism research.

OAS; W-00-01-50004; A-15-01-00000

Financial Disclosure Requirements

This review will examine FDA’s requirements on the disclosure of financial conflicts by research investigators. In early 1999, FDA issued a regulation requiring investigators to disclose financial conflicts of interest that meet or supersede certain limits. Our study will assess the prevalence of conflicts and determine the nature and extent of FDA efforts to mitigate their potential influence.

OEI; 00-00-00000
State Licensing Boards and Discipline of Physicians

We will assess the performance of State boards responsible for the licensing and discipline of physicians. The State boards serve as a vital front line of protection for Medicare and Medicaid beneficiaries, as well as all health care consumers. The boards are responsible for ensuring that practicing professionals meet the minimum qualifications spelled out in State practice acts. Because of the Health Resources and Services Administration's (HRSA) relationship with the health professions and its own quality assurance activities (such as the National Practitioner Data Bank), it has a longstanding interest in licensing board activities.

OEI; 00-00-00000

Hemophilia Treatment Centers’ Purchase of Drugs at Discount Prices

At HRSA’s request, we will examine hemophilia treatment centers’ efforts to purchase anti-hemophilic factor drugs at 340B discounted prices. Under Section 340B of the Public Health Service Act, drug manufacturers that sell to eligible PHS entities may not charge more for covered drugs than the average manufacturers’ price decreased by a rebate percentage. Hemophilia treatment centers, which are funded by HRSA, qualify for discount pricing of anti-hemophilic factor under the law. However, concerns have been raised regarding the centers’ ability to obtain discount drug prices.

OAS; W-00-01-50005; A-01-01-00000

Drug Purchasing by Ryan White Grantees and Eligible Metropolitan Areas

We will examine Ryan White Title I grantees’ and Eligible Metropolitan Areas’ knowledge and use of various strategies to purchase drugs at the lowest available cost. Eligible Metropolitan Areas are those metropolitan regions (currently numbering 51) with the highest incidence of HIV disease. We will evaluate the efficiency and cost effectiveness of current Eligible Metropolitan Areas’ drug purchasing arrangements and the level of coordination with
State AIDS Drug Assistance Programs. This study follows up on our “Ryan White Cost Containment Strategies” study (OEI-05-99-00610).

OEI: 00-00-00000

Coordination of HIV/AIDS Services by HRSA, CDC, and SAMHSA

We will examine the coordination of HIV/AIDS prevention and treatment services by HRSA’s Ryan White programs, CDC, and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Ryan White CARE Act requires the Secretary to ensure that HRSA, CDC, and SAMHSA coordinate the planning and implementation of Federal HIV programs to facilitate the local development of a complete continuum of HIV-related services. The statute also requires the Secretary to submit, no later than October 1, 1996, and biennially thereafter, a report concerning these coordination efforts, including a statement of whether and to what extent Federal barriers exist to integrating HIV-related programs. The required report has yet to be submitted.

OEI: 00-00-00000

Expected Issue Date: FY 2002

Coordinating Medicaid and Ryan White Services for People With HIV and AIDS

We will examine coordination between the Health Care Financing Administration’s Medicaid program and HRSA’s Ryan White programs. Funding 50 percent of all adults and 90 percent of all children with AIDS, Medicaid is the largest funder of HIV/AIDS care in the United States. In FY 1999, the Federal share of Medicaid spending on HIV/AIDS care was $2.1 billion, or over 21 percent of total Federal HIV/AIDS spending, and the States’ share was $1.8 billion. Ryan White Comprehensive AIDS Resource Emergency Act programs received over $1.4 billion in FY 1999, almost 15 percent of total Federal HIV/AIDS spending for the year. These State and local programs provide health care services to people not eligible for Medicaid and ancillary services for Medicaid recipients and others. Our study will examine coordination efforts at the Federal, State, and local levels and describe their impact on HIV/AIDS care.

OEI: 00-00-00000
Indian Health Service

Impact of Self-Governance on IHS Services

We will assess the effect of Indian self-governance on the Indian Health Service’s (IHS) ability to provide needed health care services to the Indian people. As tribes increasingly elect to manage their own health care through self-governance compacts, IHS must ensure that there are no limits or reductions in the direct care it provides to tribes that do not opt to provide their own care. We will determine (1) if controls are adequate to ensure that needed health care services are provided with compacting funds and (2) how nearby IHS facilities would be affected should compacting tribes be unable to adequately or fully meet the health care needs of their members.

OAS; W-00-01-50006; A-06-01-00000

Expected Issue Date: FY 2002

Tribal Self-Governance Compact Award Process

We will examine the IHS process for awarding compacts to tribes under the Tribal Self-Governance Demonstration Project. With nearly 20 percent of the IHS budget provided to Indian tribes through the compact mechanism, the agency needs to ensure that it has implemented the demonstration project as the Congress intended and has effectively used available authorities. Our review will focus on whether IHS has met key tenets of the legislative mandate.

OAS; W-00-97-50006; A-15-97-50003

Contracting With Tribes

This study will review IHS oversight of self-determination contracts with tribes. The Indian Self-Determination and Education Act of 1975 allows tribes and tribal organizations to operate their own health programs. We will focus on IHS area office operations, such as negotiating, monitoring, and reporting activities. This study will complement a recently completed review on the related subject of IHS compacts.

OEI; 00-00-00000

Recruitment and Retention of Staff

As IHS requested, we will focus on IHS problems with recruiting and retaining health care staff and attempt to provide recommendations to relieve these problems. Currently, IHS has a
10 percent vacancy rate, and understaffing is particularly acute in the areas of dental, pharmacy, and optometry services. In recent years, about one-third of departing dentists worked for IHS for less than 2 years.

OEI; 00-00-00000

Scholarship and Loan Repayment Programs

We will determine whether the recipients of IHS scholarship and loan repayment programs have fulfilled their obligations and, if not, what actions IHS has taken or should take to recover the funds awarded. Since FY 1998, IHS has awarded over $34 million in scholarships and loan repayments to recruit and retain professionals to work in its own and tribal facilities. The scholarship program encourages qualified Native American students to pursue careers in health fields, while the loan repayment program is offered to IHS health care employees in a variety of fields, including physicians, nurses, dentists, pharmacists, and mental health professionals. Both programs obligate recipients to serve at an IHS or tribal facility in return for IHS financial support.

OAS; W-00-01-50006; A-15-01-00000  Expected Issue Date: FY 2002

Facility Maintenance and Repair

At IHS’ request, we will determine, using industry benchmarks, whether current funding levels are appropriate to adequately maintain the agency’s real property inventory. The inventory, estimated by IHS to have a replacement value of $1.5 billion, includes hospitals, clinics, and health centers — all critical to meeting its health care delivery mission. According to IHS officials, the agency’s buildings are old and costly to repair and could affect the quality of care provided to program beneficiaries.

OAS; W-00-00-50006; A-15-00-50002

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 2000

As required by Superfund legislation, we will conduct this annual financial audit of the National Institute of Environmental Health Sciences' payments, obligations, reimbursements, and other uses of Superfund monies. The Institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 1999, agency
obligations and disbursements of Superfund resources amounted to $62.9 million and
$55.4 million, respectively.

OAS; W-00-01-50025; A-04-01-00000

Cancer Information Service Outreach Program

This study will review the effectiveness of the National Cancer Institute’s Cancer Information
Service outreach program. The mission of the program is to disseminate cancer information to
“the medically underserved, including minority groups and people with limited access to
health information and services.” This outreach effort has never been evaluated. Our study is
a follow-up to the recently completed review of the Cancer Information Service’s telephone
information service.

OEI; 00-00-00000

Commercialization of Intramural Biomedical Technology

This congressionally requested review will assess the adequacy of the NIH process for
providing biomedical technology developed in its intramural laboratories to the private sector
for marketing to the public. Under the Federal Technology Transfer Act of 1986, Federal
laboratories, including NIH, are mandated to collaborate with the private sector to facilitate the
transfer of Federal technology to the marketplace. Biomedical technology discovered and/or
developed in NIH intramural laboratories includes components of drugs, vaccines, devices,
and research material.

OAS; W-00-99-50025; A-15-99-50003

Recruiting Human Subjects for Clinical Trials

This study, a follow-up to our report on “Recruiting Human Subjects for Industry-Sponsored
Clinical Research,” will determine whether the recruiting environment in NIH-funded clinical
research is similar to that found in industry-sponsored research. It has been suggested that the
pressures to recruit for NIH trials are lower than those of industry and that NIH and its
investigators are unlikely to use recruiting practices that raised concern in our previous report,
such as offering financial incentives to investigators and scanning patient databases. We will
examine NIH trials to determine to what extent the same recruiting pressures are present and
what methods are used to recruit subjects.

OEI; 00-00-00000
General Clinical Research Centers

We will assess NIH’s monitoring and oversight of the General Clinical Research Centers program. The program annually provides approximately $200 million in grants to over 75 centers, generally located in university-affiliated hospitals, which conduct clinical research on human subjects. The program funds the establishment and support of the clinical infrastructure, including funding for research beds and support staff at the centers. A recent audit of a research center raised questions regarding the NIH funding process and overall monitoring of the centers.

OAS; W-00-01-50025; A-01-01-00000

Loan Repayment Programs

We will determine whether the recipients of various NIH loan repayment programs have fulfilled their obligations and, if not, the actions that have been or should be taken to recover the loan funds. Through these programs, NIH aims to recruit health professionals into the areas of general, reproductive (contraception and infertility), and AIDS research and to recruit individuals from disadvantaged backgrounds. In general, the loan repayment programs provide direct financial repayment of educational loans in exchange for a 2- to 3-year period of obligated clinical research service at NIH. Since FY 1998, these programs have awarded over $8.5 million in loan repayments. Our work will expand upon our review of NIH’s National Research Service Awards program, which found systemic problems in tracking loan obligations.

OAS; W-00-01-50025; A-15-01-00000

Expected Issue Date: FY 2002

Oversight of Employees’ Outside Activities and Potential Conflicts of Interest

We will review NIH’s oversight of employees’ outside activities and potential conflicts of interest. Under the guidance of the Office of Government Ethics, agencies are responsible for following regulations governing the behavior of Federal employees. These regulations address specific issues, including prohibitions on outside activities, potential conflicts of interest, and financial disclosure. As employees of the premier biomedical research institution in the United States, it is crucial that NIH personnel uphold the highest standards of integrity and independence.

OAS; W-00-00-50025; A-15-00-80001
Handling, Storage, and Disposal of Equipment Exposed to Hazardous Materials

We will determine whether NIH maintains adequate controls over the handling, storage, and disposal of equipment exposed to hazardous materials. The NIH uses hazardous materials in its hospitals, clinics, and research. If not properly handled, equipment exposed to hazardous material can contaminate individuals and resources. We reported in 1991 that NIH safety procedures were generally weak and frequently were not followed when moving property that had been exposed to hazardous materials.

OAS; W-00-99-50025; A-15-99-00032

Security of NIH Laboratories

At the request of the Subcommittee on Oversight and Investigations, House Committee on Commerce, we will determine whether physical security at NIH research laboratories is adequate to contain hazardous materials used in research. The Subcommittee specifically requested that we examine NIH’s security controls for bioterrorism research and controls for ensuring that physical security funds are appropriately spent.

OAS; W-00-00-50025; A-15-00-00030

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Substance Abuse Treatment Needs of Welfare Recipients

We will examine the strategies States use to address the substance abuse treatment needs of welfare recipients. States' assessments of the employability of these recipients may indicate the need for appropriate substance abuse treatment. While welfare reform legislation provided additional funding for treatment programs, this funding is unlikely to meet the increased demand expected as recipients are referred to treatment programs to ultimately become employable. In FY 1999, for example, the Substance Abuse and Mental Health Services Administration (SAMHSA) provided about $1.3 billion in block grant funds to States for substance abuse treatment and prevention. We will attempt to find promising approaches for service delivery that respond to treatment needs within resource constraints.

OEI; 00-00-00000
Community Support Program

This review will assess SAMHSA’s response to our June 1993 report on the Community Support Program. The program, which is funded at about $20 million annually, provides grants to State mental health authorities for services, research demonstrations, and projects involving consumers and families in the development of services. Our 1993 study made a number of recommendations to SAMSHA’s Center for Mental Health Services.

OEI; 00-00-00000

State Psychiatric Hospital Downsizing and Closings

This study will analyze the reduction of available patient beds in State psychiatric hospitals and the closing of such hospitals. In 1965, the Congress excluded most Medicaid payments to State mental hospitals because the Federal Government did not want to assume this historically State responsibility. This exclusion coincided with congressional intent to fund community mental health centers and other community providers through such HHS programs as the Mental Health Services Block Grant and Medicaid. From 1996 to 1999, 14 States closed 21 State psychiatric hospitals, and in 1999, 6 States reported plans to close 8 more hospitals. Our review will focus on the number of beds removed from the system, the factors behind the closings, and the impact of such closings on mental health care.

OEI; 00-00-00000

PHS AGENCIES-WIDE ACTIVITIES

Critical Infrastructure Protection

We will evaluate the efforts of the PHS agencies, including the Program Support Center, to meet requirements for safeguarding critical computer systems. Presidential Decision Directive (PDD) 63, “Critical Infrastructure Protection,” issued in May 1998, calls for a national effort to ensure the security of the increasingly vulnerable and interconnected physical and cyber-based infrastructures. Our review is part of the HHS-wide PDD 63 initiative.

OAS; W-00-00-40001; A-15-00-20002

Debt Management and Collection Services

We will evaluate debt management and collection services provided by the Program Support Center to PHS agencies. The Debt Collection Improvement Act of 1996 requires agencies to
transfer debts over 180 days delinquent to the Department of the Treasury for collection unless the debts are in a debt collection center designated by Treasury. In FY 1999, the Program Support Center received limited designation as HHS’ debt collection center for a 3-year period and collected debts totaling $190 million.

**Implementation of Government Performance and Results Act**

We will assess selected PHS agencies’ efforts to implement the Government Performance and Results Act of 1993. This act is intended to enhance the accountability of Federal programs by directing agencies to focus on program results. We will review the appropriateness of performance measures and data integrity issues related to measuring results.

**Disclosure Statements Filed by Colleges and Universities**

The OMB Circular A-21, revised May 8, 1996, requires that colleges and universities disclose their cost accounting practices by filing disclosure statements. The statements are designed to promote uniformity and consistency in the cost accounting practices followed by colleges and universities and to ensure that only allowable costs are claimed and that costs are equitably allocated to Federal projects. Our continuing reviews will determine whether disclosure statements are complete and accurate, reflect current practices, and comply with cost accounting standards and pertinent cost principles.

**Recipient Capability Audits**

At the PHS agencies' requests, we will perform recipient capability audits of new organizations having little or no experience managing Federal funds. These audits will determine the adequacy of the organizations' accounting and administrative systems and their financial capabilities to satisfactorily manage and account for Federal funds. Such reviews provide management with strengthened oversight of new grantees.
Reimbursable Audits

We will conduct a series of audits in accordance with the HHS responsibility to negotiate the indirect cost rates for approximately 95 percent of the Nation's nearly 3,000 colleges and universities. Audit cognizance requires that we perform audits at these schools, including those requested by other Federal agencies. Our audits may include activities related to the review of disclosure statements filed by universities in conjunction with the cost accounting standards incorporated in OMB Circular A-21.

OAS; W-00-01-50012; Various CINs

Indirect Cost Audits

We will provide assistance, as requested, to the Department's Division of Cost Allocation on specific indirect cost issues at selected institutions. In previous years, we reviewed such issues as library allocations, medical liability insurance, internal service funds, fringe benefit rates, and space allocations. These audits helped to substantially reduce indirect cost rates at the institutions reviewed.

OAS; W-00-01-50010; Various CINs

Followup on Nonfederal Audits

These reviews will determine whether auditees have implemented the recommendations in prior nonfederal audit reports to correct reported findings. The OIG's National External Audit Review Center has identified certain prior audits by nonfederal auditors as having circumstances that need further investigation.

OAS; W-00-01-50019; Various CINs

INVESTIGATIONS

Referrals by Office of Research Integrity

As a result of a closer relationship being forged between the OIG's Office of Investigations (OI) and the Office of Research Integrity (located in the Office of the Assistant Secretary for Health), OI expects to investigate more scientific misconduct cases referred by that Office. These matters may involve allegations of fiscal improprieties, such as embezzlement or misappropriation of funds, or other fraudulent activity, such as falsification or fabrication of research data or plagiarism of confidential materials or intellectual property. Under HHS policies, the Office of Research Integrity may not directly investigate such issues but refers them to OIG when appropriate.