



Fiscal Year 2006

## APPLICATION KIT

# Native American Research Centers for Health (NARCH)-4 GRANTS

for

## AMERICAN INDIAN AND ALASKA NATIVE TRIBES and TRIBAL ORGANIZATIONS

Department of Health and Human Services  
Public Health Service  
Indian Health Service

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## FISCAL YEAR 2006

### APPLICATION KIT INFORMATION

Enclosed is the Indian Health Service (IHS) Native American Research Centers for Health (NARCH) Grant Application Kit and instructions for completing the application. Federally recognized Tribes and Tribally sanctioned non-profit Tribal organizations or non-profit national or area Indian health boards or a consortium of 2 or more of those Tribes, Tribal organizations or health boards that want to be considered for an IHS NARCH for fiscal year (FY) 2006 must submit an application. The NARCH initiative will support partnerships of American Indian or Alaska Native (AI/NA) Tribes, Tribal organizations, or non-profit national or area Indian Health Boards, with institutions that conduct intensive academic-level biomedical and behavioral research; these partnerships are called NARCH. This grant program is established under the authority of sections 301(a) and 405 of the Public Health Service Act, as amended.

The application kit contains six parts: (1) Application Announcement for FY 2006 Native American Research Centers for Health (NARCH), (2) Brief Description of National Institutes of Health Centers or Institutes with a Research Focus Related to NARCH, (3) Supplemental Instructions for Native American Research Centers for Health (NARCH) Application and Application Form — PHS 398 (modified 4/2004) Public Health Service Grant, (4) NARCH Application checklist and coverage (5) Appendix and (6) Application Receipt Card.

**APPLICATION MUST BE RECEIVED BY CLOSE OF BUSINESS, SEPTEMBER 14, 2005.** Send the original signed copy and a copy of the application, including the PHS 398 (updated 4/2004 version) to Grants Management Branch, Division of Acquisitions and Grants Management, 801 Thompson, TMP Suite 100, Rockville, MD 20852. Also at the time of submission, send four (4) additional signed copies to arrive by close of business September 14, 2005 to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rockledge 2 Building Room 6160, MSC 7892, Bethesda, MD 20892-7720, Telephone (301) 594-7945, or zip code 20817 (for express or courier service).

Dr. James L. Bresette, Acting Project Officer, or Ms. Teresa Sappier, IHS, telephone (301) 443-0222 may be contacted regarding NARCH. Grant related business questions may be directed to Ms. Sylvia Ryan, Grants Management Specialist, Grants Management, IHS, (301) 443-5204. Questions regarding NIGMS issues and policies, may be directed to Clifton A. Poodry, Ph.D., Minority Opportunities in Research Division, National Institute of General Medical Sciences, 45 Center Drive, Suite 2AS.37, MSC 6200, Bethesda, MD 20892-6200, telephone (301) 594-3900. Questions on the review of applications may be directed to Michael R. Martin, Ph.D., Director, Division of Physiological Systems, Center for Scientific Review, telephone: (301) 594-7945.

Thank you for your interest in the Native American Research Centers for Health Grant Program.

**PART ONE**

**APPLICATION ANNOUNCEMENT**

**FOR**

**FISCAL YEAR 2006**

**NATIVE AMERICAN RESEARCH CENTER  
FOR HEALTH (NARCH)-4**

May 2005

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Indian Health Service

Native American Research Centers for Health (NARCH) Grants

**Announcement Type:** New

**Funding Opportunity Announcement:** HHS-2005-IHS-NARCH-0001

**Catalog of Federal Domestic Assistance Numbers (s):** 93.933

**Key Dates:** Release Date: May 2005  
Letter of Intent Deadline: August 1, 2005  
Application Deadline Date: September 14, 2005  
Review Date: November 2005  
Earliest Anticipated Start Date: June 1, 2006

**Due Dates for E.O. 12372:** Not Applicable

**Summary**

The Indian Health Service (IHS), with the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health, announces an initiative to support the Native American Research Centers for Health (NARCH) grant. This funding mechanism will develop opportunities for conducting research and research training to meet the needs of American Indian/Alaska Native (AI/AN) communities. The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be over \$2.2 million in FY 2006. The

actual amount may vary, depending on the response to the Request for Applications (RFA) and the availability of funds. Eligibles include Federally-recognized Indian Tribes, Tribally sanctioned non-profit Tribal organizations, Non-profit national or area Indian health boards, and consortiums of two or more of those Tribes, Tribal organizations, or health boards.

## **I. Funding Opportunity Description**

Purpose of the RFA:

The NARCH initiative will support partnerships between AI/AN Tribes or Tribally-based organizations such as the National Indian Health Board and Area Health Boards, and institutions that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH).

The purposes of the NARCH initiative are:

1. To develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, behavioral and health services research who will be competitive in securing National Institutes of Health (NIH) funding;
2. To increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and
3. To encourage competitive research linked to the health priorities of the AI/AN organizations and to reducing health disparities. These purposes will be achieved by supporting student development projects, faculty/researcher development projects, and research projects (including pilot projects) developed by each NARCH partnership.

Background:

The AI/AN Tribal nations and communities have long experienced poorer health status than other Americans. Although major gains of reducing health disparities were made in the last half of the twentieth century, most stopped by the mid 1980s (Trends in Indian Health 1998-99) and a few diseases, e.g., diabetes, worsened. ``All Indian" rates contain marked variation among the ``IHS Areas" or regions (Regional Differences in Indian Health 1998-99); variation by Tribe exists within Areas as well. The Trends and Regional Differences reference can be found at the IHS website at <http://www.ihs.gov/publicInfo/publications/index.asp>. Although the ``All Indian" mortality rates for all cancers are about 20 percent lower than the U.S. rates for all races, there is variation among IHS Areas for specific cancers; moreover, the favorable AI/AN mortality rates for some cancers may be due to markedly lower incidence rates partly offset by higher case-fatality rates. Unfamiliarity with modern health care may adversely influence health status among the elderly, the low-income elderly, and Tribes, and also may reduce the acceptability of health research among them. The daunting tasks confronting Tribes, researchers, and health care and public health programs in the beginning of the twenty-first century are to resume the reduction of health disparities that had occurred up to the 1980s, to reverse the worsening in a few diseases, to maintain and strengthen the favorable status, and to reduce the disparities among and within Areas and Tribes. Factors known to contribute to health status and disparities are complex, and include underlying biology, physiology, and genetics, as well as ethnicity, culture, socioeconomic status, gender/sex, age, geographical access to care, and levels of insurance. Additional factors known to contribute to health status and disparities include:

1. family, home, and work environments;
2. general or culturally specific health practices;
3. social support systems;
4. lack of access to culturally- appropriate health care; and
5. attitudes toward health.

Yet none of these alone or in combination accounts for all documented differences. Health disparities of AI/ANs may also reflect a lack of research relevant to improve their health status. Many AI/ANs distrust research for historical reasons. One approach that combats this distrust is to ensure that Tribes are senior partners in training and research that involves them, as for example in community-based participatory research. This approach is especially helpful to design both training relevant to researchers from Tribal communities, and research relevant to the health needs of the communities.

Research Objectives: Due to the complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services (HHS) and the collaboration of researchers and AI/AN communities, are needed to achieve significant improvements in the health status of AI/AN people. To accomplish this goal, in addition to objectives set by the Tribe, Tribal Organization or Indian Health Board, the IHS NARCH program will pursue the following program objectives:

A. To develop a cadre of AI/AN scientists and Health Professionals- -Offering opportunities to develop more AI/AN scientists and health professionals engaged in research, and to conduct biomedical, clinical, behavioral and health services research that is responsive to the needs of the AI/AN community and the goals of this initiative; Faculty/ researchers and students at each proposed NARCH will develop investigator-initiated, scientifically meritorious research projects, including pilot research projects, and will be supported through science education projects designed to increase the numbers of, and to improve the research skills of, AI/AN investigators and investigators involved with AI/ANs.

B. To enhance Partnerships--Recent community-based participatory research suggests that AI/AN communities can work collaboratively in partnership with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status.

C. To Reduce Health Disparities--In the amended Indian Health Care Improvement Act, Public Law (Pub. L.) 94-437, IHS was legislatively mandated to improve the delivery of effective health care to AI/ANs. In the NIH Revitalization Act of 1993, NIH was encouraged to increase the number of under-represented minorities participating in biomedical, clinical, and behavioral research, including studies on drug abuse and alcoholism, and the examination of the role of resiliency in the prevention and treatment of those conditions. Also, the "Initiative to Eliminate Racial and Ethnic Disparities in Health" by HHS (<http://www.omhrc.gov/rah>) encouraged NIH to

help reduce health disparities. In response to these priorities, the IHS and NIH have established a collaboration to support Native American Research Centers for Health.

Reducing health disparities among AI/AN communities and individuals may be fostered by greater understanding of how to enhance their strengths and resilience. While AI/AN communities have relied on health research and medical science to reduce health disparities, they also have relied on their own psychological, organizational, and cultural assets and strengths to survive major harms and disruptions over the centuries, and to rebound from insults to health.

The mission of NIH is to acquire new knowledge that will lead to better health by understanding the processes underlying health and disease that in turn will help prevent, detect, diagnose, and treat disease and disability. The NARCH initiative works toward the NIH mission by supporting research that discovers the interrelationships among the many factors that contribute to health and disease, and by helping train and promote researchers concerned with AI/AN health.

## **II. Award Information**

### **1. Mechanism(s) of Support**

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS. This funding opportunity will be reviewed using the NIH SO6 mechanisms. The responsibility for planning, directing, and executing the program, as well as data acquisition and analysis and evaluation of the proposed program, lies with the applicant organization.

### **2. Funds Available**

The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be over \$ 2.2 million in Fiscal Year 2006. The actual amount may vary, depending on the response to the RFA and availability of funds. An application may request a project period not to exceed four years of support, and direct costs not to exceed \$800,000 in the first year. Direct costs to the applicant include the entire cost of each subcontract--that is, each subcontract's direct cost plus the subcontract's appropriate Facilities and Administration (F&A) cost. Because it is anticipated that all budget requests will exceed \$250,000, the modular grant requirements would not apply to this RFA.

The maximum grant period may not exceed four years, with the opportunity for a competing renewal at the end of that period.

## **III. Eligibility Information**

The proposed NARCH must be a working partnership of the AI/AN organization and of the research-intensive institution. Applicants eligible to receive a NARCH award are the AI/AN organizations of the partnerships. As the grantee, the AI/AN organization will define criteria and eligibility for participation in all aspects of the partnership, consistent with this announcement. A minimum of 30 percent of the grant funds must remain with that AI/AN organization, that is, no more than 70 percent may be subcontracted to other institutions or organizations.

### 1. Eligible Applicants

The AI/AN applicant must be one of the following:

- A. A federally recognized Indian Tribe; or
- B. A Tribally sanctioned non-profit Tribal organization; or
- C. A non-profit national or area Indian health board; or
- D. A consortium of two or more of those Tribes, Tribal organizations, or health boards.

### 2. Cost Sharing or Matching

Cost sharing or matching is not required.

### 3. Other Requirements

#### A. The Research-Intensive Partner:

The Research-Intensive Partner must be an accredited public or private nonprofit university or other institution that has an established record of conducting research into the health problems of AI/AN; has demonstrated a commitment to enhancing the capability of AI/AN faculty/researchers, students, investigators, and communities to engage in biomedical, behavioral, clinical and health services research; and has demonstrated a commitment to mentoring AI/AN faculty/researchers, students, and investigators.

#### B. Principal Investigator:

The Principal Investigator, the individual responsible for the administration (including fiscal management) of the overall project, must have his/her primary appointment with the AI/AN applicant organization. Special arrangements of employment, such as inter-organizational personnel agreements, are permissible. The Principal Investigator may be, but is not required to be, the NARCH Program Director or a Research Project Investigator.

#### C. NARCH Program Director:

The NARCH Program Director is the individual responsible for the day-to-day leadership and management of the research and training programs within the proposed NARCH. The Program Director may be, but is not required to be, the Student and Faculty/Researcher Development Director or a Research Project Investigator.

#### D. Student and Faculty/Researcher Development Director and Participants:

The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on the continual development of students and faculty/researchers. In order to be included as the Student and Faculty Development Director, the prospective director must have a faculty/researcher appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner, and must demonstrate that he/she has the knowledge, skills, and capabilities to mentor students and faculty/ researchers and to generate and direct development and mentoring programs.

The Student and Faculty Development Director may be the NARCH Program Director. Faculty/researchers and students should be supported in research education activities that improve their skills and abilities to be successful at the next stage of their professional development. To be included as a participant for faculty/researcher development in the proposed

NARCH, the individual must have a faculty/ researcher appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner.

#### E. Research Project Investigators:

The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on continual improvement of the research competitiveness of the research investigators. In order to be included as a research project investigator in the proposed NARCH, a prospective investigator must have a faculty appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner, and must show that he/she has the need, based on institutional, departmental, and professional development plans, to enhance his/her research knowledge, skills, and capabilities by engaging in the proposed research program and associated activities.

#### F. Tribal Approval of the Application:

It is the policy of the IHS that all research involving AI/AN Tribes be approved by the Tribal governments with jurisdiction. Therefore, the following documentation is required as part of the application:

- For a federally recognized Indian Tribe--a resolution of support from the Tribal government must be part of the application. Applications that involve more than one Indian Tribe must include resolutions of support from all participating Tribes.
- For an eligible consortium of Tribes--a resolution of support from each Tribe of the consortium must be included.
- For a Tribally sanctioned non-profit Tribal organization--specific Tribal resolution(s) of support will not be required if the current Tribal resolution(s) under which the organization operates encompasses the proposed application. (A copy of the current operational resolution(s) must be submitted with the application.)

An official signed resolution must be received by the Division of Grants Operations, IHS, at the Reyes Building, 801 Thompson Avenue, TMP 100, Rockville, MD 20852. A grant will not be awarded unless the signed resolution is received.

For a Non-profit national or area Indian health board, or a consortium of those eligible Indian health boards--a resolution is not required. However, the applicant organization must submit a letter of support signed by the executive director of each health board involved, specifically citing the research project proposed. Each AI/AN organization that derives benefit from the grant must also submit such a letter.

#### G. Mechanism of Support:

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS, and will be reviewed using the NIH S06 mechanism.

## **IV. Application and Submission Information**

### 1. Address To Request Application Package



NARCH Program Official, Reyes Building, 801 Thompson Avenue, Rockville, MD 20852. Applicants are strongly encouraged to establish eligibility of their proposed applications prior to submission. Inquiries about eligibility should be addressed to Timothy L. Taylor, Ph.D., at (301) 443-1549. The application package will be posted on the IHS Research Program Website, at: <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm> .

The NIH PHS 398 application instructions are available at: <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) Telecommunications for the hearing impaired: TTY 301-451-0088.

There will be no acknowledgment of receipt of the application.

## 2. Content and Form of Application Submission

A. A proposed NARCH may include any or all of the following components: student development projects; faculty/researcher development projects; research projects (including pilot projects); and “core” administrative facility.

B. The content of the application should explain the components of the application, and how they help meet the purposes of the NARCH initiative. A description should be provided of the current state of the research and research training enterprise at the proposed NARCH and its institutional and community partners, including faculty/researcher and student profiles.

A clear statement should be presented of the overall goals, specific measurable objectives, and anticipated milestones. These elements should be presented in the context of needed improvements in the partners' organizational infrastructure and environment for research. Documentation should be provided to establish that the research-intensive partner is an institution with a record of conducting research into the health of AI/ANs, and that it has a demonstrated commitment to the special encouragement of, and assistance to, AI/AN faculty/researchers, students, investigators, and communities for enhancing their capacity to engage in biomedical, behavioral and health services research. Documentation about the nature of the partnership itself should be included, such as: the process to develop the application and proposed NARCH itself, the past and future efforts to increase the capacity of the partners to improve their partnership, and to contribute to the success of the NARCH.

A plan for assessment of the benefits of the activities by the proposed NARCH on specific, measurable outcomes identified in the application should be provided. IHS and NIGMS recognize that Tribes, Tribally-based organizations, and research- intensive institutions are diverse in their missions, their health and economic status, and their cultures. Such an assessment could include a self-study by the proposed NARCH and its partners, which focuses on fact-finding, program evaluation, and recommendations for improvement in key areas. Strategies for determining the initial and ongoing success of their efforts for organizational development should also be presented. It is expected that each proposed NARCH will develop its own set of strategies that best match its circumstances. Guidance and suggestions for program

evaluation of a proposed NARCH can be obtained from <http://www.the-aps.org/education/promote/promote.html>

Applicants are strongly urged to contact NARCH initiative staff at an early stage to request the specific supplementary instructions for the PHS 398 for the NARCH grants. Supplementary instructions may be obtained from the initiative contacts listed under VII. Agency Contacts, and will be posted at:

<http://www.ihs.gov/MedicalPrograms/Research/narch.cfm>.

### **"DUNS" number**

Applications must be prepared using the PHS 398 research grant application instructions and forms (revised 9/2004). As of October 1, 2003, applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the Web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact Grants Info, Telephone (301) 435-0714, e-mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov). Internet applications for a DUNS number can take up to 30 days and this could cause organizations to lose opportunities to apply, or delay them until the next round. It is significantly faster to obtain one by phone. You will need the following information to request a DUNS number:

- Organization name
- Organization address
- Organization telephone number
- Name of CEO, Executive Director, President, etc. (The person in charge)
- Legal structure of the organization
- Year organization started
- Primary business (activity) line
- Total number of employees.

C. The RFA label available at <http://grants1.nih.gov/grants/funding/phs398/label-bk.pdf> in the PDF format must be affixed to the bottom-face page of the application. Type this RFA number: ``NOT GM-05-104" on the label. Failure to use this label could delay processing the application and it may not reach the review committee in time for review. In addition, the ``Native American Research Centers for Health" and the RFA number must be typed on line 2 of the face page of the application form and the YES box must be marked.

D. If *Student Development Projects* are proposed, the NARCH application should describe new programs, modifications or additions to existing programs of the partners that encourage and facilitate AI/AN students to enter, advance, and remain in research careers. Such projects might include, but are not limited to, providing employment as research assistants in research projects of research-active mentors with an explicit mentoring plan, providing other mentoring with an explicit mentoring plan, providing workshops to improve technical or communication skills, providing motivating seminars or journal clubs highlighting problems of interest to students, providing contact with role models, and providing opportunities to travel to present results at national scientific meetings. If research mentorships or apprenticeships are proposed, the application should clearly document the experience, proposed commitment, and quality of the

mentors in providing guidance and advice to students (including responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and/or community-based AI/AN researchers.

The application should describe how the development plans for the student will meet both the individual's professional development goals, and one purpose of the NARCH initiative: to develop a cadre of AI/AN scientists and health professionals. The application must have an evaluation plan for the project(s) that indicates the anticipated outcomes relative to the current baseline data. For example, one outcome might be the improved retention of students in science majors. The application should indicate the anticipated (quantitative) improvement relative to the current retention rate.

A student in a NARCH Student Development Project must be a full- time or part-time student officially enrolled in an educational program leading to an undergraduate or graduate degree, or in a post-doctoral educational program, or (if well justified) in late high school. A helpful book about mentoring science students is found at <http://books.nap.edu/catalog/5789.html>.

E. If ***Faculty/Researcher Development Projects*** are proposed, the NARCH application should describe the need, proposed activity, and anticipated outcomes. Faculty/researcher development projects might include, but are not limited to, short-term mentored research experiences in the lab of an active NIH-extramurally-funded researcher with an explicit mentoring plan, long-term general mentoring under an explicit mentoring plan, or attendance at workshops or courses or national meetings needed for acquiring specific skills or methodologies needed for prospective research. As with student development projects, the application should document the experience, proposed commitment, and quality of the mentors, teachers, or experience in providing guidance and advice to faculty/researchers, and in fostering the development of academic and community-based AI/AN research. The application must also describe the evaluation plan for the faculty/researcher development project. The application must clearly describe how the development plans for faculty/researchers will meet both the individual's professional development goals, and two purposes of the NARCH initiative:

- to develop a cadre of AI/AN scientists and health professionals, and
- to enhance the partnership of the proposed NARCH.

F. NARCH applications may include a maximum of five (5) regular ***Research Projects*** and a maximum of five (5) ***Pilot Research Projects***. Unlike regular research projects, a pilot research project is limited in scope and is not expected to have preliminary data. It is also limited to a budget of no more than \$50,000 direct costs per year for four years. The pilot research project is intended for faculty/researchers without current federal research support. Support for faculty/researchers participating in pilot research projects is preparatory to seeking more substantial funding from NIH research grant programs (e.g., Academic Research Enhancement Award [AREA], K, and R01 awards), as well as funding from other agencies and private sources. Funds received from the proposed NARCH to support pilot research projects may not be used to supplement ongoing research projects. A NARCH application need not include both research projects and pilot research projects. Applications for only pilot research projects or for only research projects may be submitted. Individual project investigators may propose either a research project or a pilot research project, but not both.

Research projects (including pilot research projects) proposed under this initiative must be in research areas normally funded by any of the National Institutes of Health. Research projects addressing health disparities and the health priorities of the AI/AN partner are especially encouraged.

A listing of grants recently funded by NIH may be found at CRISP (Computer Retrieval of Information on Scientific Projects), a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. It may be accessed at (<http://ott.od.nih.gov/crisp.html>).

Each research project or pilot research project should follow the instructions provided in PHS 398 (revised 9/2004) for preparing research grant applications. The professional development goals must clearly describe specific objectives and milestones which should include, but are not limited to, improving competitiveness in acquiring grant support. The applicant should describe how successful completion of the proposed research project will improve the research skills, and will help develop the students and faculty/researchers, thus contributing to the overall goals and specific measurable objectives of the proposed NARCH.

Each research project or pilot research project must follow the IHS policy concerning Tribal approval, that all research involving AI/AN Tribes be approved by the Tribal governments with jurisdiction. That is, each grantee must include a resolution of approval from the Tribal government[s], or (if applicable) a letter of support signed by the director of the eligible AI/AN organization, or both (if applicable) for projects that involve people or community[ies] of an AI/AN Tribe, or an eligible non-profit organization.

### 3. Submission Dates and Times

#### A. Letter of Intent Deadline: August 1, 2005.

Prospective applicants are asked to submit a letter of intent that includes the title of the proposed NARCH, the name, address, and telephone number of the Principal Investigator and its Program Director, the identities of the partners and of key personnel, and the number and title of this RFA. The letter of intent should be received before 6 p.m. EST on May 1, 2005, by Mushtaq A. Khan, D.V.M., Ph.D., Chief, Digestive and Respiratory Sciences IRGs, Center for Scientific Review, MSC 7818, Room 2176; 6701 Rockledge Drive; Bethesda, MD 20892 (20817 for Fed Ex) Phone: (301) 435-1778; Fax (301) 451-2043; E-Mail: [KHANM@CSR.NIH.GOV](mailto:KHANM@CSR.NIH.GOV).

Letters may be submitted by mail, fax or e-mail. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the IHS and NIH Center for Scientific Review (CSR) staffs to estimate the potential review workload and avoid conflict of interest in the review.

#### B. Application Deadline: September 14, 2005.

The applications must be received before 6 p.m. EST on September 14, 2005. If an application is received after that date, it will be returned to the applicant without review. To be considered timely, an application must be sent on or before the deadline date. If sent timely (with

documented proof of mailing) but received after the deadline, an application will be accepted for review only if it is received in time for orderly processing. Competing applications not meeting the deadline date specified in the announcement are considered late applications and will not be considered for funding under that announcement. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

#### 4. Intergovernmental Review

This funding opportunity is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." A State approval is not required.

#### 5. Funding Restrictions

Grantees are allowed a reasonable period of time in which to submit required financial and performance reports. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions, or cause other eligible projects or activities involving that grantee organization, or the individual responsible for the delinquency to not be funded. Failure to obtain prior approval for change in Scope, Principal Investigator, Grantee Institutions, Successor in Interest, or Recipient Institute Name, undertaking any activities disapproved or restricted as a condition of the award, may result in fund restrictions.

#### 6. Other Submission Requirement

The administrative personnel, facilities, and programs of the overall NARCH should be described. It is permissible, but not necessary to have a set of core support programs that provide common scientific services to two or more NARCH projects. Submit a typed and signed original application, including the Checklist, and one (1) single-sided photocopy of the entire application (including Appendices and supporting documents) in one package to: Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP 100, Rockville, MD 20852-1627 (zip code is unchanged for express/courier services), Telephone: (301) 443-5204.

Also, at the time of submission, send four (4) additional single-sided photocopied and signed applications, including the Checklist, Appendices, and supporting documentation to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6160- -MSC 7892, Bethesda, MD 20892-7720, Bethesda, MD 20817 (for express or courier service). Telephone: (301) 435-0715.

### **V. Application Review Information**

Upon receipt, IHS and NIH staff will administratively review applications for completeness and responsiveness. Applications that are incomplete, non-responsive to this RFA, or do not follow the guidelines of the PHS form 398 (revised 9/2004) or of the supplementary instructions for NARCH grants, will be returned to the applicant without further consideration. Applications will be evaluated in accordance with the criteria stated below for scientific and technical merit by appropriate peer review groups convened by the CSR. The National Advisory General Medical Sciences Council will conduct the second level of review.

## 1. Criteria

Priorities for funding will be based on the scientific and technical merit of the application, the assessed potential of investigators in the developmental stages of their careers, and the likelihood that the proposed NARCH can further the purposes of the NARCH initiative. Awards will be made only to organizations with financial management systems and management capabilities that are acceptable under PHS policy. Awards will be administered under the PHS Grants Policy Statement.

## 2. Review and Selection Process

### A. Review of Student and Faculty/Researcher Development Plans:

The anticipated effectiveness of the proposed NARCH in making a difference relative to the current base-line data (based in part on previous experience of the partners) will be assessed. Factors to be considered include:

The appropriateness of the content, phrasing, quality, and duration of the student or faculty/researcher development plans in the NARCH application to achieve the scientific development of the faculty/researcher, post-doctoral, pre-doctoral, undergraduate, and (if well justified) high school students; and

The experience, proposed commitment, and quality of the mentoring plan and of individual mentors of the partners in providing mentoring, guidance, and advice to candidates (including training in responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and community-based AI/AN researchers.

### B. Review of Research Projects:

The NIH has announced procedures to be used for the review of research grant applications (NIH Guide, Volume 26, Number 22, June 27, 1997 or see <http://grants.nih.gov/grants/guide/notice-files/not97-010.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html> (for additional updated information). For NARCH applications, the five criteria listed in this announcement will be used for the scientific review of research projects and pilot research projects. The review of research projects and pilot research projects will be the same except that applications for pilot studies may be smaller in scope and would not be expected to have preliminary data.

In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these purposes. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- **Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- The adequacy of plans, if research on human subjects is involved, to include both genders and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
- The reasonableness of the proposed budget and duration in relation to the proposed research.
- The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.
- The adequacy of the proposed plan to share data, if appropriate.

In reviewing the overall Center, the initial scientific review group will examine evidence of the partners' commitment to the purposes of the NARCH initiative to develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, behavioral and health services research that is competitive for Federal funding; to increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and to encourage competitive research linked to the health priorities of the AI/AN partner and to reducing health disparities.

The evidence will include:

- The quality of the partnership of the institutional and community partners, and the quality of the involvement of the Community and Scientific Advisory Council, as demonstrated by documentation of (for instance): the intellectual and tangible contributions and



activities of the partners, and of the Council, in developing the application and the proposed NARCH; the interactions of the partners, and of the members of the Council, in meetings (such as those to develop the application and proposed NARCH); the past activities and future plans to increase the capacity of the partners and of the Council; the plans for future contributions and activities by the partners, and by the Council, in furthering the goals of the proposed NARCH; and the plans for future development of the partnership itself;

- The experience and commitment of the institutional and community partners to recruit, retain, and advance AI/AN faculty/ researcher and students, to support faculty/researcher and student research efforts, and to increase the role of the involved AI/AN communities in the plans of the proposed NARCH;
- The appropriateness of the plan for evaluating the impact of the proposed NARCH, including the quality of baseline data and milestones for accomplishments, and a system to track the future course of program participants; and
- The potential of the proposed NARCH to be a regional and national resource, including: Capacity to provide quality research training and mentoring for integrated promotion and development of AI/AN research careers from undergraduate (or if well justified, high school) through post-doctoral levels; attainment of quality research linked to health priorities of the AI/AN partner and to reducing health disparities; plans for research information dissemination and education activities; and plans for the development of research networks to support the scientific aims of the proposed NARCH.

### 3. Anticipated Announcement and Award Dates

Anticipated Announcement Date: May 2005.

Earliest Anticipated Award Date: June 1, 2006.

## **VI. Award Administration Information**

### 1. Award Notices

Grants Management will not award a grant without an approved application in conformance with regulatory and policy requirements and which describes the purpose and scope of the project to be funded. When the application is approved for funding, the Grants Management Office will prepare a Notice of Grant Award with special terms and conditions binding upon the award and refer to all general terms applicable to the award.

### 2. Administrative and National Policy Requirements

#### Authority and Regulations

This program is described in the Catalog of Federal Domestic Assistance at: <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of 301(A) and 405 of the Public Health Service Act. Awards will be subject to OMB Circulars, HHS Grant Regulations at 45 CFR, Pt. 74 and 92. The grant will be administered under the PHS Grants Policy Statement and other applicable agency policies, IHS and NIH policies and procedures.



Also, see Senate Appropriations Committee Report, No. 92-316, July 29, 1971, Executive Order 12900, Educational Excellence for Hispanic Americans February 22, 1994, Executive Order 12876, Historically Black Colleges and Universities, November 1, 1993, and Executive Order 13021, October 21, 1996, and Outline of Work Plan, August 18, 1998, White House Initiative on Tribal Colleges and Universities. Applications are not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### A. Inclusion of Women and Minorities in Research Involving Human Subjects:

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical, clinical, behavioral and health services research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of P.L. 103-43). Because the NARCH initiative targets AI/ AN people and communities, a minority population, only the policy of inclusion of women applies to this RFA. The IHS has fully accepted the OHRP policy regarding human subjects. The OHRP website is <http://www.hhs.gov/ohrp/>. All investigators proposing research involving human subjects should read the UPDATED ``NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>). The complete Guidelines are available at:

[http://grants1.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants1.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The revisions relate to NIH defined Phase III clinical trials and require:

- All applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and
- All investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

#### B. Inclusion of Children as Participants in Research Involving Human Subjects:

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects' research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted. All investigators proposing research involving human subjects should read the ``NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>. Investigators may obtain copies of these policies from the initiative staff listed under VII. Agency Contact. Initiative staff may also provide additional relevant information concerning the policy.

#### C. URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should

not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

#### D. Public Access to Research Data Through the Freedom of Information Act:

The OMB Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are:

- First produced in a project that is supported in whole or in part with Federal funds; and
- Cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA.

It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

#### E. Allowable Administrative Costs:

Certain administrative costs for managing a comprehensive program are allowable and may vary, depending upon the size and complexity of the program's activities. The costs budgeted for NARCH grants and subcontracts may not duplicate items already budgeted in other cost centers of the AI/AN, research-intensive, and subcontracted organizations and institutions, such as accounts which make up the Facilities and Administration (F&A) cost pool. The grantee organization receiving the award must be prepared to provide documentation showing the direct relationship of proposed costs to the program, and that costs of this type are charged in a uniform manner to all other grants at all institutions and organizations participating in the award. Salary (up to 25 percent effort, although it should generally be less) for the NARCH Program Director is allowable for that portion of time or effort specifically employed in directing the proposed NARCH. (The 25 percent limit does not include salary for being a research investigator.) Limited salary support for secretarial or clerical help is allowable only when in direct support of the proposed NARCH. For guidance, applicants should refer to the OMB Circular appropriate for them, A-87 (Cost Principles for State, local, and Indian Tribal Governments), at <http://www.whitehouse.gov/omb/circulars> or A-122 (Cost Principles for Non-Profit Organizations), <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://http://www.whitehouse.gov/omb/circulars>, or should contact the grants management officer listed under VII. Agency Contacts.

Costs for evaluation activities are allowable, as are costs for the Community and Scientific Advisory Council. All applications must include costs associated with one annual meeting per year in Rockville, MD, of NARCH directors and their key scientific personnel. Applications

should also include costs associated with attendance at the annual IHS Research conference for key personnel and trainees.

**Student Development Costs:** Student (graduate, undergraduate, and high school if well justified) remuneration through salary/wages for participation in research experiences may be requested, provided all the following conditions are met:

- The student is performing necessary work involved in the research.
- There is an employer-employee relationship between the student and the proposed NARCH or its partners.
- The total compensation is reasonable for the work performed.
- It is the practice of the proposed NARCH or its partners to provide compensation for all students in similar circumstances, regardless of the source of support for the activity.

Graduate students, but not undergraduate students, are allowed tuition costs as part of a compensation package. When requesting support for a graduate student, the NARCH application should provide, in the budget justification section of the application, the basis for the compensation level. The IHS staff will review the requested compensation level and, if it is reasonable and justified, will provide compensation up to a maximum of \$45,000 (<http://grants.nih.gov/grants/guide/notice-files/not98-168.html>). Post-doctoral students should be compensated at a rate commensurate with that of other post-doctoral employees with similar degrees and experience at the research-intensive institution. It is the expectation of the IHS and NIGMS that students who are enrolled in a accredited graduate program, as part of a proposed NARCH, will not be excluded from support from other non-Federal or Federal graduate training sources (such as loans and assistance under the Veterans' Adjustment Benefit Act or Pell Grants) for which they are eligible.

Graduate and post-doctoral students cannot concurrently hold another federally-sponsored stipend or fellowship or any other Federal award that duplicates the NARCH support.

**Faculty/Researcher Development Costs:**

Costs to support faculty/researcher development activities, such as workshops or courses, national meetings, or short-term research experiences in the laboratory of an active NIH-extramurally-funded researcher needed for acquiring specific skills or methodologies needed for prospective research, are allowable. Such costs might include tuition, travel and per diem costs, as well as salary support appropriate to the percent effort needed for the activity.

**Research Project Costs:**

Direct costs associated with research and pilot research projects are allowable when adequate justification is provided. These include faculty/researcher salaries, reimbursed according to percent effort. Summer salary support can be paid provided the institution's academic schedule permits such release and when the institution approves. The maximum summer-salary support provided by the program cannot exceed the equivalent of three months at 100 percent effort, or time specified by the institution as its policy. Grant funds may not be used to increase or supplement faculty/ researcher academic year salaries. Salary support for technical assistance

and costs for consultants, if justified, are allowable. Costs for equipment to be used to carry out the proposed research are allowable.

#### Costs for Core Scientific Services:

Costs for core scientific services to support two or more projects are allowable. Costs for multi-user research equipment are also allowable. A plan for access to the multi-user equipment, its maintenance, management and use must be included. To aid in the review, it is suggested that a tabular summary show the estimated or actual proportional use of this equipment by each project, and other investigators and students. Justify this core component by discussing ways in which these centralized services improve quality, bring about an economy of effort, and/or save overall costs as compared to their inclusion as part of each research project. Personnel costs to maintain and service the equipment are an allowable cost. Support for very large pieces of equipment, however, may be restricted by the NARCH budget. Plans to maintain the shared core scientific services and facility beyond the grant period should be discussed.

#### Cost for Supplies:

Costs for supplies, including costs for animals necessary to carry out the proposed research, may be included. Travel costs for the investigator(s) are permitted when direct benefits to the program are expected, and when adequate justification is provided. Alterations and Renovations costs (up to \$40,000) are allowable only when essential for conduct of the proposed research. Other permitted costs include animal maintenance (unit care costs and number of care days), donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, and service contracts.

#### Consortium and Contract Arrangements:

Consortium arrangements that may involve personnel costs, supplies, and other allowable costs, including F&A costs; contractual costs for support services, such as the laboratory testing of biological materials, clinical services, data processing, or core administrative services, are allowable expenses. Consortia and contractual costs with Native health organizations, Tribes and/or research institutions in Canada or Mexico are allowable expenses.

#### Pilot Research Projects:

The intent of pilot research projects is to lead to regular research projects funded as part of the center grant or as freestanding grants. For pilot research projects, applications may request support for up to \$50,000 (direct costs) per year. This support is non-renewable.

#### Subcontracts:

The grant recipient may issue subcontracts to other organizations (such as the research-intensive institution of the partnership), as long as at least 30 percent of the grant remains with the AI/AN organization; that is, no more than 70 percent may be subcontracted.

#### F. Unallowable Costs:

Unallowable costs for research projects (including for pilots projects) include costs for student development, textbooks, journals, memberships, and Internet subscription costs, as well as other costs prohibited by OMB Circulars A-87 or A-122 as applicable. Employees of the applicant organization may not serve as paid consultants but may be paid. The pilot research project is intended for faculty/researcher without current Federal research support. Therefore, investigators with significant current support from other mechanisms such as the R01 and research funding from other extramural sources are not eligible, and the costs therefore are not allowable. Release time for preparing proposals or mini-research projects, not submitted as pilot projects, is not allowed.

#### G. Qualifications of the NARCH Program Director and Key Personnel:

As leader of the research and research training for the proposed NARCH, the NARCH Program Director is expected to possess certain essential qualifications such as:

- Strong leadership skills, including scientific leadership experience and a strong academic and scientific background, as exemplified, ideally, by scientific publications and a record of peer-reviewed scientific support;
- Knowledge of and personal working relationship with the AI/AN Tribes or communities involved in the NARCH research, and with the partners of the proposed NARCH;
- Strong mentoring and supervision skills, to exercise responsibility for mentoring activities, organization of communicating skills programs, special methods workshops, tracking of student career plans, etc.; and
- Knowledge of IHS and NIH policies, including those concerning human participants in research, human biological material, animals, hazardous materials, and Tribal review and approval of research.

The names and qualifications of the NARCH Program Director, the Student and Faculty/Researcher Development Director and directors of individual projects within the program (where appropriate), and any other key personnel, should be listed in the application under the Key Personnel section. Biographical Sketches of these individuals, including other grant support, should be included.

#### H. Human Subjects Protection:

Federal Regulations (45 CFR, Pt. 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)

#### I. Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a PHS led national activity for setting priority areas. This Request for Application (RFA) announcement is related to one or more of the priority areas. Potential applicants may obtain a copy of Healthy People2010 at: <http://www.healthypeople.gov>.

### 3. Reporting

The NARCH Program Office and Grants Management have requirements for the progress reports and financial reports based on the terms and conditions of the grant. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due annually. Financial Status Reports (SF 269) are due 90 days after each budget period and the final SF 269 must be verified from the grantee records on how the value was derived. Grantees are allowed a reasonable period of time in which to submit required financial and performance reports.

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions, or cause other eligible projects or activities involving that grantee organization, or the individual responsible for the delinquency to not be funded.

Failure to obtain prior approval for change in Scope, Principal Investigator, Grantee Institutions, Successor in Interest, or Recipient Institute Name, undertaking any activities disapproved or restricted as a condition of the award, may result in fund restrictions.

### **VII. Agency Contact(s)**

1. Questions on the initiative, regarding IHS NARCH issues and policies, may be directed to: Timothy L. Taylor, Ph.D., Director of Planning, Evaluation and Research, Indian Health Service, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852-1750, Telephone: (301) 443-0222, Fax: (301) 443-1522, e-mail: [ttaylor@hqe.ihs.gov](mailto:ttaylor@hqe.ihs.gov).

2. Questions on grants management and fiscal matters may be directed to: Sylvia Ryan, Division of Grants Operations, Indian Health Service, Reyes Building, 801 Thompson Avenue, Rockville, MD 20852-1627, Telephone: (301) 443-5204, Fax: (301) 443-9602, e-mail: [sryan@hqe.ihs.gov](mailto:sryan@hqe.ihs.gov).

3. Questions on NIGMS issues and policies, may be directed to: Clifton A. Poodry, Ph.D., Minority Opportunities in Research Division, National Institute of General Medical Sciences, 45 Center Drive, Suite 2AS.37, MSC 6200, Bethesda, MD 20892-6200, Telephone: (301) 594-3900, Fax: (301) 480-2753, e-mail: [poodryc@nigms.nih.gov](mailto:poodryc@nigms.nih.gov).

4. Questions on the review of Applications may be directed to: Mushtaq A. Khan, D.V.M., Ph.D., Chief, Digestive and Respiratory Sciences IRGs, Center for Scientific Review, MSC 7818, Room 2176; 6701 Rockledge Drive; Bethesda, MD 20892 (20817 for Fed Ex) Telephone: (301) 435-1778; Fax: (301) 451-2043; e-mail: [khanm@csr.nih.gov](mailto:khanm@csr.nih.gov).

### **VIII. Other Information**

Technical Assistance Workshops:

The IHS and NIH intend to conduct technical assistance and information sharing workshops about this grant initiative in July 2005 at one regional center. Potential grantees wanting to attend

one of these workshops will have to provide names and the eligible organization to Ms. Sylvia Ryan, at telephone number (301) 443-5204 or Fax (301) 443-9602, or by e-mail to [sryan@hqe.ihs.gov](mailto:sryan@hqe.ihs.gov) as soon as possible and no later than March 15, 2005. This notification will help the IHS and the NIH to determine the best times and locations for potential grantees' training and to have adequate workshop supplies. The details of the workshops and locations will be posted (as they are finalized) on the IHS Research Program Web site at <http://www.ihs.gov/medicalprograms/research>.

### **References for Background Information:**

Anderson, N.B. Levels of analysis in health science: A framework for integrating sociobehavioral and biomedical research. *Annals of the New York Academy of Sciences*, 1998, 840, 563-576.

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Macaulay, A.C., Commanda, L.E., Freeman, W.L., Gibson, N., McCabe, M.L., Robbins, C.M., & Twohig, P.L., (for the) North American Primary Care Research Group. Participatory research maximizes community and lay involvement. *British Medical Journal*, 1999, 319, 774-778.

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*Trends in Indian Health 1998-99*. Program Statistics Team, Office of Public Health, Indian Health Service, 2001.

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Williams, M.V., Parker, R.M., Baker, D.W., Parikh, N.S., Pitkin, K., Coates, W.C., & Nurss, J.R. Inadequate functional health literacy among patients at two public hospitals. *Journal of the American Medical Association*, 1995, 274, 1677-1682.

Dated: April 22, 2005.

**Charles Grim,**

*Assistant Surgeon General Director, Indian  
Health Service.*

[FR Doc. 05-8465 Filed 4-28-05; 8:45 am]

**BILLING CODE 4165-16-U**



## **PART TWO**

### **Internet Links to Various National Institutes of Health Centers or Institutes with a Research Focus Related to NARCH Grants**

May 2005

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National Cancer Institute (NCI) - <http://www.nci.nih.gov/aboutnci/overview/mission>

National Center for Complementary and Alternative Medicine (NCCAM) –  
<http://nccam.nih.gov/about/aboutnccam/index.htm>

National Center on Minority Health and Health Disparity (NCMHD) –  
[http://www.ncmhd.nih.gov/about\\_ncmhd/mission.asp](http://www.ncmhd.nih.gov/about_ncmhd/mission.asp)

National Heart, Lung, and Blood Institute (NHLBI) –  
<http://www.nhlbi.nih.gov/about/org/mission.htm>

National Human Genome Research Institute (NHGRI) – <http://www.genome.gov/10001022>

National Institute of Allergy and Infectious Diseases (NIAID) –  
<http://www.niaid.nih.gov/facts/overview.htm>

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) –  
<http://www.niams.nih.gov/an/index.htm>

National Institute of Child Health and Human Development (NICHD) –  
<http://www.nichd.nih.gov/about/about.cfm>

National Institute of Dental and Craniofacial Research (NIDCR) –  
<http://www.nidcr.nih.gov/AboutNIDCR/MissionStatement.htm>

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) –  
<http://www.niddk.nih.gov/welcome/mission.htm>

National Institute of Environmental Health Sciences (NIEHS) – <http://www.niehs.nih.gov/>

National Institute of General Medical Services (NIGMS) – <http://www.nigms.nih.gov/>

National Institute of Mental Health (NIMH) – <http://www.nimh.nih.gov/about/index.cfm>

National Institute on Alcohol Abuse and Alcoholism (NIAAA) –  
<http://www.niaaa.nih.gov/about/mission.htm>

National Institute on Drug Abuse (NIDA) – <http://www.nida.nih.gov/About/AboutNIDA.html>

The Agency for Healthcare Research and Quality (AHRQ) –  
<http://www.ahrq.gov/about/budgtix.htm>

The Centers for Disease Control and Prevention (CDCP) - <http://www.cdc.gov/about/default.htm>

# **PART THREE**

## **Supplemental Instructions**

**and**

## **Internet Link to Application Form (PHS 398, Revised 9/2004)**

May 2005

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### **Supplementary Instructions for Native American Research Centers for Health (NARCH) Applications in 2005**

Since the NARCH applications can be quite complex, please follow the instructions in the PHS 398 application except where noted below. Please note that it is essential to use the most current version of application forms and instructions for the PHS 398 (Revised 9/2004). Use of the electronic versions, downloaded directly from NIH, is strongly encouraged. These can be found at: <http://grants.nih.gov/grants/funding/phs398/phs398.html> .

#### **SECTION I – PHS 398 GENERAL INFORMATION REQUIREMENTS**

**I. FACE PAGE** (Use Form PHS 398 Face Page) (Form Page 1).

Item 1. Title of Project. The title should be related to the overall thrust of the program (e.g. IHS NARCH Program at \_\_\_\_\_ Tribe and \_\_\_\_\_ University) and not to a particular research or student development project.

Item 2. Response to Specific Request for Application or Program Announcement. Check the box marked “YES”. Under “Number” type in “NOT GM-05-104” and under “Title” type in the words “Native American Research Centers for Health (NARCH)-4”.

**II. DESCRIPTION, PERFORMANCE SITES AND KEY PERSONNEL** (Use Form PHS 398 Form Page 2). In preparing the abstract of the proposed program, in addition to the instructions given in Form PHS 398, outline the overall program goals and objectives,

anticipated outcomes and how the proposed research projects relate to achieving these objectives and the goals of the IHS NARCH Program.

**III. TABLE OF CONTENTS (Form Page 3)**

Reviewers may find the application easier to read if the pages in the NARCH applications are arranged in the order shown in the *Sample* Table of Contents below. Pages should be numbered consecutively at the bottom throughout the application. Do **not** use suffixes for page numbers, such as 5a, 5b.

<i><b>SAMPLE</b></i>	
<b>TABLE OF CONTENTS</b>	
<b><u>SECTION 1 PHS 398 GENERAL INFORMATION REQUIREMENTS</u></b>	
I.	FACE PAGE..... 1
II.	DESCRIPTION, PERFORMANCE SITES AND PERSONNEL..... 2
III.	TABLE OF CONTENTS..... 3
IV.	ADMINISTRATIVE BUDGET..... 4
V.	OVERALL SUMMARY BUDGET..... 5
VI.	BIOGRAPHICAL SKETCH OF NARCH DIRECTOR..... 6
VII.	OTHER SUPPORT (FOR NARCH DIRECTOR ONLY)..... 7
VIII.	INSTITUTIONAL SETTING AND GENERAL PLAN..... 8
<b><u>SECTION 2 (2a., 2b., 2c., etc.) – FORMAT FOR EACH RESEARCH PROJECT/PILOT</u></b>	
IX.	FACE PAGE..... —
X.	DESCRIPTION, PERFORMANCE SITES AND PERSONNEL..... —
XI.	TABLE OF CONTENTS..... —
XII.	ADMINISTRATIVE BUDGET..... —
XIII.	OVERALL SUMMARY BUDGET..... —
XIV.	BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR ..... —
XV.	OTHER SUPPORT (FOR PRINCIPAL INVESTIGATORS ONLY)... —
XVI.	INSTITUTIONAL SETTING AND GENERAL PLAN..... —
<b><u>SECTION 3 CHECKLIST (Use Form PHS 398)..... —</u></b>	

**IV. ADMINISTRATIVE BUDGET**

**V. OVERALL BUDGET SUMMARY**

General Budget Instructions for Section IV and V

NARCH proposals should submit two types of budgets:

- (1) Overall administrative budget and
- (2) Budgets for each of the projects.

Each budget must consist of two separate parts:

- (1) Detailed Budget for the First 12-Month Period (PHS 398 Form Page 4) and
- (2) Budget for the Entire Proposed Project Period (PHS 398 Form Page 5).

Place the administrative budget pages (2 pages) and the overall program summary budget (2 pages) after the page showing the table of contents. The budget pages for individual research projects and pilot research projects (each 2 pages) are placed at the beginning of each individual project.

Label each budget page in the bottom right hand corner (i.e., “Administrative Budget” “Overall Program Summary Budget” or “Project # - Name of Investigator”).

Follow the budget guidelines in Form PHS 398 instructions. The budget items should be described in detail, and justify the need for all requested items. Do **NOT** assume that the need is obvious.

An overall summary of the estimated costs for the entire project period must be included on this page. The total direct and indirect costs for the entire project period should be entered under item 8 on the face page.

The total direct and indirect costs for the first 12-month period should be entered under item 7 on the face page.

Entire Project Period (PHS 398 Form Page 5)

**VI. BIOGRAPHICAL SKETCH FOR NARCH DIRECTOR** (Use PHS 398 Form Page)

**VII. OTHER SUPPORT (FOR NARCH DIRECTOR ONLY)** (Use “Other Support” format.)

There is no "form page" for other support. Information on other support should be provided in the *format* shown at <http://grants.nih.gov/grants/funding/phs398/othersupport.pdf> , using continuation pages as necessary.)

**VIII. INSTITUTIONAL SETTING AND GENERAL PLAN** (Use PHS 398 Continuation Pages)

**A. Description of the Partnership**

(Do not exceed four pages, not including tables and graphs.)

The information below must also be provided in the application. This information is necessary for determining the appropriateness of the environment for a NARCH program.

1. Describe the origins and development of the collaboration through the submission of the application.
2. Briefly summarize, in tabular Form, for each of the past four years, the distribution of American Indian/Alaska Native students and faculty (number and percentage) for the whole partner institution and for each NARCH Program participating school and/or department.
3. Provide brief evidence of the academic institution's commitment to the hiring of American Indian/Alaska Native faculty (including those in science departments) and to the training of American Indian/Alaska Native students. Briefly describe and summarize any significant achievements within the last three years of any specialized programs at the institution that have encouraged and have helped to recruit/retain American Indian/Alaska Native students and faculty in the NARCH Program participating departments.
4. Provide a brief summary, by year and American Indian/Alaska Native group, of the degrees awarded by each proposed NARCH participating department for the last four years. Use a separate table for undergraduate and graduate students.

**B. Proposed NARCH Program Plan and Its Anticipated Value to the Partnership**

(Do not exceed four pages, not including tables and graphs.)

Provide a concise description of goals and objectives of the overall NARCH program. Clearly state how the proposed NARCH Program will enhance/assist the partnership's efforts to provide expanded opportunities for American Indians/Alaska Natives in biomedical and health services research, and to strengthen the institutional research and research training capability. Describe specific measurable improvements, anticipated as a consequence of the NARCH grant, in faculty accomplishments (e.g. publications, grant applications, grant funds, etc.). Provide a brief overview of the research interests, stage in research career (beginning, established, retooling, etc.) and potential for growth (improvement) of the faculty members applying for research support as well as availability of senior faculty willing and able to serve as mentors. Describe the probable research career goals (e.g. ability to successfully participate in open competition for research grants) for the individual investigators beyond successful completion of the proposed research project. Describe the plans and activities to develop the partnership and the capacities of the individual tribal and institutional partners, from the submission of the application through the end of the proposed program. Sufficient information should be provided so that a proper review can be conducted, e.g., 1) specific objective(s), 2) rationale for and feasibility of the proposed activity, 3) detailed description of the activity, including a timetable if appropriate, and 4) resources available.

**SECTION 2 – FORMAT FOR EACH PROJECT PROPOSED (WHETHER FOR STUDENT DEVELOPMENT, FACULTY DEVELOPMENT, RESEARCH, OR PILOT RESEARCH)**

(Each Project should have all eight of the parts listed below, where appropriate, collected together by project)

**I.** The following FACE PAGE format replaces a PHS 398 face page for each individual project.

**Investigator(s):** The Project Investigators should be listed first followed by collaborating investigators, if any, which should be listed in alphabetical order.

**Type of Application:** Indicate whether the project is a student development project, faculty development project, regular research project, or pilot research project.

**Protection Against Research Risks:** Provide the appropriate information for the proposed research project. See Form PHS 398 instructions for information required when human subjects or vertebrate animals are involved. Where hazardous conditions or substances are involved, details for training and protecting workers must be included in Part 4 of the Research Plan: Experimental Design and Methods, Form PHS 398.

*SAMPLE FACE PAGE FORMAT*

**NARCH INDIVIDUAL PROJECT**

1. Descriptive Title: (80 characters or less)

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2. Investigator(s)

Last Name

First Name

MI

Degree

Departments

---

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3. Type of Project:

Student Development Project

Faculty Development Project

Regular Research Project

Pilot Research Project

4. Protection Against Research Risks:

A. Will Human Subjects be involved? Yes  No

[ ] If yes, what is the status of IRB review? Completed  Documentation Enclosed

Pending

5. Vertebrate Animals

A. Will Vertebrate Animals be used? Yes  No

[ ] B. If yes, list the species \_\_\_\_\_ and estimate the number to be used \_\_\_\_\_

If yes, what is the status of IACUC review? Completed  Documentation Enclosed

[ ] Pending

6. Are there potential hazards to laboratory workers (carcinogens, pathogens, ionizing radiation, etc.) involved in the proposed research? No  Yes  If yes, identify these below:

- A.
- B.
- C.
- D.

**COSTS**

7. Costs Requested for Initial Budget Period

A. Direct Costs (\$) \_\_\_\_\_

B. Total Costs (\$) \_\_\_\_\_

8. Costs Requested for Proposed Period of Support

A. Direct Costs (\$) \_\_\_\_\_

B. Total Costs (\$) \_\_\_\_\_



**II. DESCRIPTION, PERFORMANCE SITES AND PERSONNEL** (Use Form PHS 398 Form Page 2)

**III. BUDGETS** (Use Form PHS 398 Form Pages 4 and 5)

Prior to preparation of budgets for each project, please carefully review the Form PHS 398 instructions and also additional instructions included herein. Allowable costs are outlined in the NARCH Request for Application. Pay careful attention to instructions for budget justification on pages 11-13 and on page 5 of Form PHS 398. Justification of budget items should be presented on Page 5 of Form PHS 398 and any continuation page(s) required. Individual budget items should be combined in preparing the Overall Summary Budget, Section I, V.

**Personnel:** Technical assistant(s) should be listed separately. An explanation of the fringe benefits and rates should be given. The cited rate should be applicable for all employees based on their classification as full time, part-time, or temporary status.

**IV. BIOGRAPHICAL SKETCH FOR EACH PROJECT INVESTIGATOR**

(Use Form PHS 398 Biographical Sketch Format page)

**V. OTHER SUPPORT FOR EACH PROJECT INVESTIGATOR** (Use "Other Support" format.)

There is no "form page" for other support. Information on other support should be provided in the *format* shown at <http://grants.nih.gov/grants/funding/phs398/othersupport.pdf>, using continuation pages as necessary.)

**VI. RESOURCES** (Use Form PHS 398, Resources Format Page)

**VII. PUBLICATIONS** (Use Form PHS 398, Continuation Pages)

**VIII. PROJECT PLAN** (Use Form PHS 398 Continuation Pages)

**Option A: If a Student Development Project is proposed:**

Provide detailed information on plans to provide opportunities for students to become acquainted with and to participate in biomedical or health services research, including interaction with American Indian/Alaska Native role models.

Information required includes: 1) specific objective and goals, 2) rationale for and feasibility of the approach chosen, 3) detailed description of the activity, 4) plan for attracting desired student pool, 5) resources available, including commitments and other expressions of interest by off-campus scientists, laboratories and/or other facilities, 6) description of faculty/student involvement, and 7) evaluation plans and other follow-up activities. Include timetables.

Examples of supportable student developmental efforts are on-campus research, seminars, workshops, and informal discussions by visiting scientists, attendance at

regional and national scientific meetings, and participation in off-campus laboratory, clinical or health services research and/or didactic research activities at other institutions conducting high quality research. Other developmental activities may also be supported.

Describe how students are to be selected to participate in developmental activities, specifying the criteria to be used.

**Option B: If a Faculty Development Project is proposed:**

Provide detailed information on plans to provide opportunities for selected faculty. For each activity include the name, faculty rank, and tenure status, along with: 1) specific objective(s), 2) rationale for and feasibility of the proposed activity, 3) detailed activity description, including a timetable if appropriate, 4) resources available for activities involving participation in an active research group shall include letters of commitment and other expressions of interest by the PI at the potential on-campus or off-campus facilities, and 5) plans for establishing collaborative or other follow-up activities.

**Option C: If a Regular Research Project is proposed:**

Follow Form PHS 398 instructions, including page limitations. The sequential format should be:

Introduction, Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design and Methods, Human Subjects, Vertebrate Animals, Consultants/Collaborators, Consortium/Contractual arrangements, Literature Cited.

**Option D: If a Pilot Project Research Project is proposed:**

Follow Form PHS 398 instructions, including page limitations. The sequential format should be:

Introduction, Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design and Methods, Human Subjects, Vertebrate Animals, Consultants/Collaborators, Consortium/Contractual arrangements, Literature Cited.

**SECTION 3 CHECKLIST** (Use Form PHS 398)

**SECTION 4 APPENDIX** (List in TABLE OF CONTENTS and item included in APPENDIX)



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE**

**Grant Application -**

**<http://grants.nih.gov/grants/funding/phs398/phs398.html>**

**PHS 398 (Revised 9/2004)**

*See the [11/2/2004 NIH Guide Notice](#) for important changes to this version.*

*All notable changes made to PHS 398 form pages are listed at the [bottom of this page](#) (Updated 4/26/2005).*

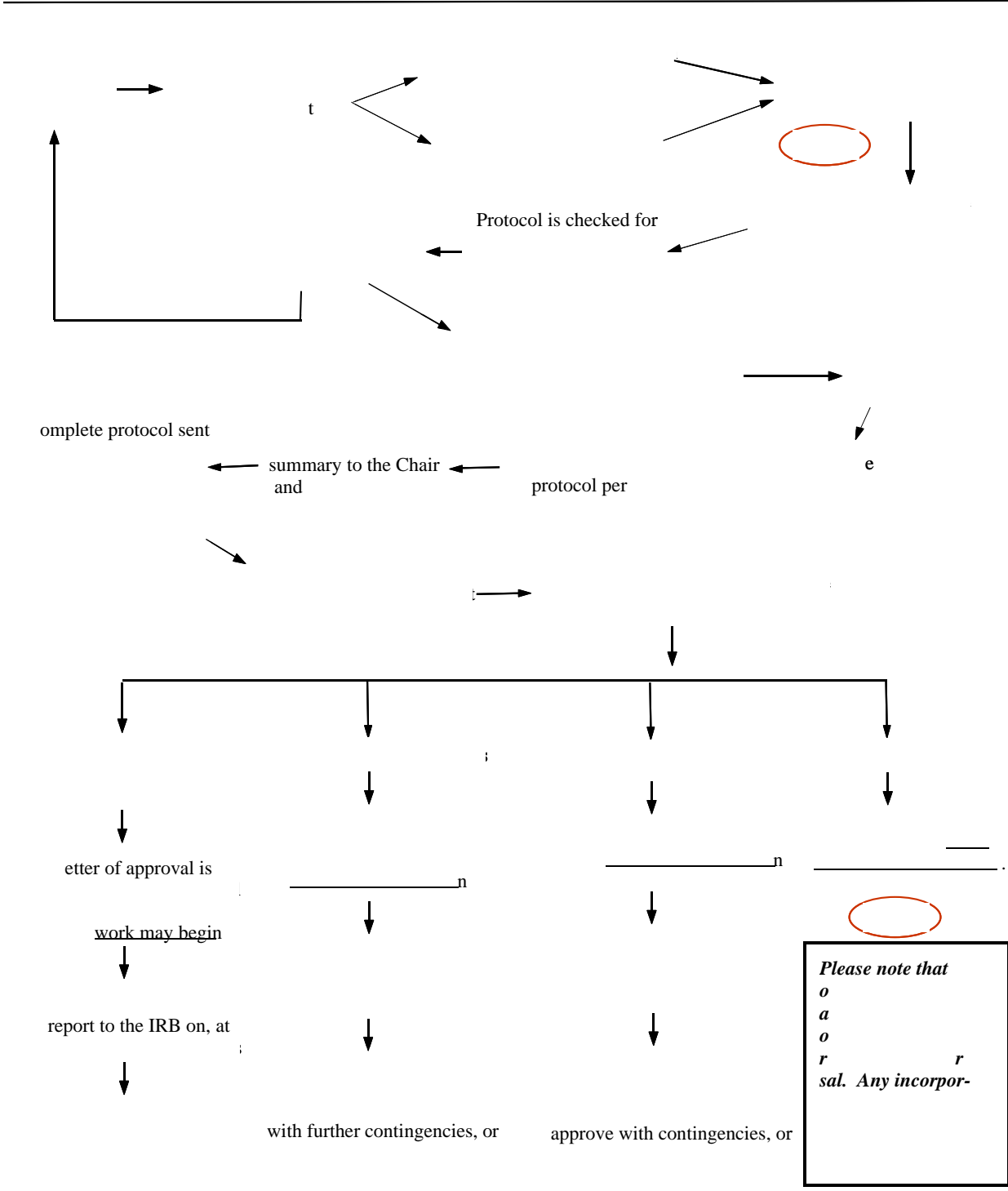
# **PART FOUR**

## **APPENDIX**

May 2005

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- IRB Flowchart
- HIPAA
- Allowable and Unallowable Costs
- PHS Grants Policy Statement Article 2.7,  
**Costs** Under PHS Grant Supported Projects or Activities (PHS GPS 9505)



## *Institutional Review Boards and the HIPAA Privacy*

### *Overview*

The Privacy Rule, at 45 CFR parts 160 and 164, establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by an Institutional Review Board (IRB) or a new type of review body, a Privacy Board.

An IRB's authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirement is new and in addition to, not in lieu of, the traditional IRB authorities to protect research participants from risks under 45 CFR part 46 (Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects) and 21 CFR parts 50 and 56 (Food and Drug Administration (FDA) Regulations on Protection of Human Subjects). Other Federal and State laws and regulations may impose other or additional restrictions and limitations on the use of health information for research that may not be waived or altered by an IRB or Privacy Board under the authority granted to it by the Privacy Rule.

This fact sheet is limited to the Privacy Rule's requirements relating to an IRB and approvals of research-related requests for Authorization waivers or alterations and how those requirements relate to the functioning of an IRB under 45 CFR part 46, 21 CFR parts 50 and 56, and other Federal laws and regulations applicable to an IRB. A separate fact sheet entitled *Privacy Boards and the HIPAA Privacy Rule* discusses the concurrent authority of Privacy Boards established under the Privacy Rule to approve such waivers or alterations. Additional information about the Privacy Rule can be found in the booklet *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.*

For guidance on the Privacy Rule, see the HHS Office for Civil Rights (OCR) Web site at <http://www.hhs.gov/ocr/hipaa>. For guidance on the interpretation of HHS or FDA Protection of Human Subjects Regulations at 45 CFR part 46 or 21 CFR parts 50 and 56, respectively, visit the Office for Human Research Protections (OHRP) Web site at <http://ohrp.osophs.dhhs.gov/> or the FDA Web site at <http://www.fda.gov/oc/gcp>, respectively.

For additional information, see:

- [Privacyruleandresearch.nih.gov/irbandprivacyrule.asp](http://www.privacyruleandresearch.nih.gov/irbandprivacyrule.asp) HTML version - Posted August 15, 2003 (revised 9/25/03)
  - [View PDF version of entire document](#) - Posted August 15, 2003 (revised 9/25/03) (File size: 216KB)
  - [View RTF version of entire document](#) - Posted August 15, 2003 (revised 9/25/03) file size: 88KB

## Allowable and Unallowable Costs

This appendix includes a chapter from the Public Health Service (PHS) Grants Policy Statement and provides guidance on what is allowable and unallowable as costs for the Grants for Special Programs, i.e. Diabetes Program grants for Indians. They have direct application to the NARCH grantees and can be used as a guide in using the grants funds. It is provided here as a reference guide since there has been a number of specific costs that have been questioned as to allow ability under this program. They are as follows:

**Alteration and Renovation (A&R)**-----ALLOWABLE in accordance with the PHS Grants Policy Statement. Note that the amount that may be used for A&R is limited to the lesser of \$150,000 or 25% of the total funds expected to be awarded for direct costs under the grant for three consecutive budget periods. If a grantee is to request A&R, the renovations must be to an existing building that is to be used for the diabetes project and that is suitable for human occupancy. Additional documentation is required for the IHS to approve requested A&R, in excess of \$50,000, i.e., line drawings of existing space and proposed changes. See pages 7-2 to 7-4 for specific requirements. If the space is leased that will be altered/renovated, the length of the lease should allow for its use for the entire period of the grant award.

**Construction**-----UNALLOWABLE. The program legislation, Section 330C of the Public Health Services Act, as amended, does not authorize construction (see page 7-5 for definition). Building a jogging/running track or a swimming pool is considered construction and is unallowable. If you have tribal or other Federal monies available that may be used for construction, you may include them as a tribal contribution to the grant and use them.

**Other Expenses**-----ALLOWABLE. Grant funding may be used to pay subjects to complete a survey that will collect information on diabetes issues, e.g., life style preferences. A minimal payment (not to exceed \$15 per individual completing a survey) is allowable. The grantee should keep a listing of subjects who were paid for their participation.

**Supplies**-----ALLOWABLE. For purposes of this diabetes program, incentive items may be purchased with grant funding for participants in such activities as health fairs, fitness programs, fun runs, etc. Items

must be of nominal value (less than \$10/per item) such as caps, T-shirts, water bottles, and posters.

**Cash prizes or gifts are not allowable.**

**Rental or Lease of Facilities and Equipment**-----ALLOWABLE. Rental or lease is allowable if the space or item is necessary to carry out the grant program and the costs are reasonable (see page 7-11). The IHS is neither a party to the lease agreement nor responsible for conditions, terms, or payment of rents or leasing fees.

**Trailers and Modular Units**-----ALLOWABLE FOR TRIBES AND URBANS. Under this grant program, these units are considered as equipment to be used at a given location site for the project period of the grant only. **Such units are not to be permanently installed.** The grantee must obtain a Government-issued revocable license if the proposed site is located on federally to owned or managed land. See pages 7-13 to 7-14.

The **IHS entities** serving as grantees must contact the **Area Realty Officer or Ms. Eleanor Matney**, Principal Realty Officer, Division of Facilities and Environmental Engineering, at (301) 443-5954 regarding use of rental space or trailers/modular units. These IHS entities must comply with Federal policies.

## **7. COSTS UNDER PHS GRANT-SUPPORTED PROJECTS/ACTIVITIES**

### **(PHS GPS 9505)**

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Costs borne in whole or in part by a PHS grant, and any non-Federal matching required by the terms of the grant, are considered to be "project costs" and are subject to the cost principles and the policies in this section. Under the total approved budget concept, any expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grant in the same proportion as the Federal/non-Federal participation in the overall budget.

Applicants for discretionary grants are expected to anticipate and justify their funding needs and the activities to be carried out with those funds in preparing the budget and accompanying narrative portions of their applications. Unless otherwise indicated on the Notice of Grant Award (NGA), a discretionary award based on the information included in the approved grant



application constitutes the required prior approval referred to in several of the following sections. Post award requests to incur costs or undertake activities that are not described in the approved application and that require prior approval are subject to the requirements in section 8, "Changes in Expenditures/Activities." **(1)**

The project costs comprise the allowable direct costs incident to performance of the grant activities plus the allocable portion of the allowable indirect costs of the organization, less applicable credits. A direct cost is any cost that can be specifically identified with a particular project or program. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the project or activity. Indirect costs are those incurred by an organization for common or joint objectives and cannot be identified specifically with a particular project or program. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that are usually treated as indirect costs. All costs must be reasonable and necessary.

An important element in all phases of the grants administration process--pre-award, award, and post-award--is the identification of allowable costs. The basis for determining the allow ability and allow ability of costs charged to PHS grants and cooperative agreements is set forth in 45 CFR Part 74, Subpart Q, and 45 CFR Part 92.22. Five separate sets of cost principles, based on type of organization, are prescribed for recipients and cost-type contractors: **(2)**

- State, local, and federally recognized Indian tribal governments (OMB Circular A-87)
- Institutions of higher education (OMB Circular A-21)
- Hospitals (45 CFR Part 74, Appendix E)
- Nonprofit organizations **(3)** (OMB Circular A-122)
- For-profit (commercial) organizations (Federal Acquisition Regulation--48 CFR Subpart 31.2.)

Each recipient or contractor is subject only to the set that applies to its type of organization. A sub grantee or contractor under a grant is subject to the cost principles applicable to its type of organization, which may not necessarily be the same as that of the grantee.

The cost principles permit an organization to establish and use its own accounting system to determine costs, provided it is based on sound accounting principles consistently applied to all organizational activities regardless of the source of funds supporting those activities. Although costs may be charged as either direct or indirect depending on their identifiable benefit to a project or program, such costs must be treated consistently for all work of the organization under similar circumstances so as to avoid duplicate charges.

## ALLOWABLE AND UNALLOWABLE COSTS

Organizations must have procedures for determining the allow ability of costs to grant-supported activities and projects according to the applicable cost principles and other terms of the award. Outlined below are those costs generally allowable and unallowable as project costs under PHS discretionary grant programs, including both direct and indirect costs.

This section is not exhaustive; the cost principles should be consulted for more specific guidance. This section also addresses certain cost items that are not specifically covered in the cost principles or elsewhere and, in some cases, supplements the language in the principles.

Aside from the cost principles and supplemental policies in this section, the allow ability of costs may be subject to additional requirements specified in the program legislation and regulations and in the specific terms of an award.

This section applies to grantees and, where applicable, to sub grantees. It does not apply to contractors under grants unless the language for a given provision indicates otherwise. However, as stated earlier, the applicable cost principles do apply to such contractors.

If grantees are uncertain whether a particular cost is allowable, they should contact the GMO of the appropriate PHS awarding office.

**Advertising**--Allowable only for recruitment of staff or trainees, procurement of goods and services, disposal of scrap or surplus materials, and other specific purposes as indicated in the terms of the award necessary to meet the requirements of the grant-supported project or activity.

**Alcoholic Beverages**--Generally not allowable unless authorized in the approved project and consistent with the purpose of the award.

**Air Conditioning Equipment**--Allowable.

**Alteration and Renovation**--Alteration and renovation (A&R) is defined as work required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment so that it may be more effectively utilized for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. A&R costs that do not constitute construction are allowable charges to PHS grant-supported projects and activities.

Routine maintenance and repair of the organization's physical plant or its equipment are not considered to be A&R. Certain costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames in order to place equipment in its permanent location or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs depending on the recipient accounting system and are allowable.

New construction is unallowable unless specifically authorized by the program legislation ([see "Construction" and appendix 2](#)). A&R projects in an existing building that are considered construction, such

as relocation of exterior walls, roofs, and floors; attachment of fire escapes; development and repairing of parking lots; or completion of unfinished shell space to make it suitable for human occupancy are unallowable unless authorized by the program legislation.

Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost.

Subject to the limitations set forth below, A&R costs may be charged to PHS grant-supported projects provided that--

- The program legislation or implementing regulations or other grant terms do not exclude "alteration and renovation."
- The grantee is not an individual or a foreign institution.
- The grant is not a conference grant.
- The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required.
- The A&R is essential to the project supported by the grant.
- The space involved will actually be occupied by the project.
- The space is suitable for human occupancy before A&R work is started, except where the purpose of A&R is to make the space suitable for some purpose other than human occupancy (e.g., storage).
- If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed.
- The amount charged does not exceed the following limitations:
  - The amount budgeted or used for A&R under a single grant during three consecutive budget periods (whether or not the 3 years overlap two distinct competitive segments of support) cannot exceed the lesser of \$150,000 or 25 percent of the total funds reasonably expected to be awarded by PHS for direct costs for such 3-year period, unless a waiver is obtained from the awarding office.
  - The maximum amount of PHS grant funds that may be applied to any single A&R project is \$150,000.
  - The amount of project funds re-budgeted for A&R during a budget period cannot exceed \$50,000 without prior approval from the PHS awarding office.

A&R costs under programs that have statutory A&R, modernization, or facilities assistance authority are limited to the costs of modifying existing space and utilities within a completed and finished structure that is suitable for human occupancy. The cost of adapting any of the following interior building features to the needs of the grant-supported activity is allowable under these programs.

- Physical characteristics of space, such as interior dimensions, surfaces, and finishes
- Internal environment, such as heating, ventilation, humidity, and acoustics
- Utility services, such as plumbing, electricity, gas, vacuum, or other laboratory piping

- Unfinished shell space to make it suitable for purposes other than human occupancy, such as the storage of pharmaceuticals
- Fixed equipment, such as casework, fume hoods, large autoclaves, or biological safety cabinets

A&R costs of this type associated with a building under construction or an otherwise incomplete structure may be allowed if the space is to be adapted to particular program needs, it is cost effective to perform such work while the building is being constructed or the structure is being completed, and the A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting the space and utilities to meet specific program requirements.

If any A&R would affect the accessibility for physically handicapped persons, then all parts of the building that are altered must comply with the General Services Administration Accessibility Standard (October 14, 1980).

Two copies of the following documents are to be submitted with each request for approval of A&R costs in excess of \$50,000 (whether proposed in the application or as a post award re-budgeting request):

- A single line drawing of existing space and proposed alterations.
- A narrative description of the proposed functional utilization of the space and equipment requirements prepared by the persons who will use and be responsible for the working space, e.g., the program and administrative managers and, when appropriate, architectural and engineering advisors. Final drawings and specifications will be based on this description.

The description should include a detailed explanation of the need, character, and extent of the functions to be housed in the space for A&R, using the following headings, as appropriate:

- General information
- Description of the functions to be performed in the space
- Space schedule (detailed description of floor space)
- List of fixed equipment proposed for the facility
- Cost estimate (see details in appendix 3)
- Special design problems
- Description of the existing and proposed utility systems for the modified space
- Description of plans to provide accessibility for the physically handicapped
- Provisions for meeting the requirements of the Life Safety Code
- The length of the property lease if the space is rented
- Other information required by program legislation or regulations

- When the proposed alteration is to occur in a building that is under construction or in an incomplete structure, the following documentation must also be provided:
  - A detailed justification for the need to perform the work before the building is completed
  - A cost comparison between doing the work before and after the building is completed
  - A description of other specific benefits to be gained by doing the work before the building is completed
- When the request is for more than \$75,000 per budget period, and if requested by the PHS awarding office, grantees should submit, in addition to the information above, a copy of architectural and engineering documents, including the following:
  - The final cost estimate
  - Coded architectural floor plans showing the final arrangement of space committed to the PHS program
  - Final working drawings and specifications
  - The design analysis report, describing the heating, ventilation, air conditioning, plumbing, and electrical power systems
  - Provisions to meet mandatory Federal requirements and special clearances

When the recipient's own construction and maintenance staff is used in carrying out the A&R, i.e., force account, the associated costs are allowable provided the grantee can document that force account is less expensive than contracting, and all costs are substantiated by appropriate receipts for the purchase of materials and certified pay records for the labor involved.

**Animals**--Allowable for the acquisition, care, and use of experimental animals. If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the Cost Analysis and Rate Setting Manual for Animal Resource Facilities (NIH Pub. No. 80-2006, October 1979).  
[\(4\)](#)

**Audiovisual Activities**--Allowable. "Audiovisual" means any product containing visual imagery or sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery or sound or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing.

Under PHS discretionary grants (or sub grants under discretionary grants), written prior approval must be obtained from PHS, which will in turn seek, as appropriate, approval from the HHS Office of the Assistant Secretary for Public Affairs to use project funds to acquire or produce audiovisuals if the cost of any single audiovisual, including the reported non-Federal share, exceeds or is expected to exceed \$25,000 and if the cost is to be treated as a direct cost.

The requirement for prior approval does not apply to the production or acquisition of films, videotapes, filmstrips, or slides that are under sub grants or lump sum awards; under research and research training grants in which the productions are to be used as research or research training instruments; under

research grants for the purpose of documenting experimentation or research findings, provided they are not intended for release to, or use with, the general public; and for the purpose of placing captions for the deaf or hearing impaired on films or videotapes not originally produced for use with deaf or hearing impaired persons.

A recipient having in-house production capability must determine if it would be more efficient and economical to use that capability or to contract for the production of an audiovisual ([see section 8, "Procurement"](#)).

If an audiovisual intended for general public audiences (i.e., persons who are not health professions personnel and who are not directly involved in project activities either as employees, providers of health services to patients, or other participants such as volunteers or patients) is produced under a PHS grant-supported project, the recipient must submit two prints or tapes of the finished product along with its annual or final progress report ([see section 8, "Reporting"](#)). The costs of such prints or tapes are allowable project costs.

Audiovisuals produced under a PHS grant-supported project must bear an acknowledgment and disclaimer, as appropriate, such as:

The production of this motion picture (television program, etc.) was supported by Grant No. \_\_\_\_\_ from (name of awarding agency). Its contents are solely the responsibility of (name of grantee organization) and do not necessarily represent the official views of (name of awarding agency).

**Audit Costs**--Allowable. The charges may be considered a direct cost when the audit scope is limited to a single PHS grant-supported project or the audit scope includes more than one project, but the costs can be specifically identified with and allocated to each project on a proportionate basis, and this practice is followed consistently by the grantee; otherwise, charges for audits should be treated as indirect costs.

**Bad Debts**--Not allowable.

**Bonding**--Allowable. See 45 CFR Part 74, Subpart C, and 45 CFR Part 92.36 for policies and requirements concerning bonding.

**Books and Periodicals**--Allowable as a direct cost when required for the conduct of the project. Where an institution has a library, books and periodicals should generally be provided as normal library service and treated as indirect costs rather than being directly charged.

**Child Care Costs**--Allowable to assist patients in receiving health services and to permit consumer board members to attend board meetings ([see "Consumer/Provider Board Participation"](#)). Such costs may also be allowable as a fringe benefit for individuals working on a grant-supported project ([see "Fringe Benefits"](#)).

**Communications**--Allowable as direct costs incurred for local and long distance telephone calls, telephone surveys, telegrams, postage, etc., but only when they can be specifically identified to the project and are consistently treated as direct costs. Otherwise, they should be treated as indirect costs.

**Conference Grant Costs**--Allowable only as specified in [appendix 7](#).

**Conference Services**--Allowable under conference grants for necessary recording of proceedings, simultaneous translation, subsequent transcriptions, and other similar costs.

**Construction**--Allowable only when the program legislation includes specific authority to construct facilities and PHS specifically authorizes such costs.

**Allowable and unallowable construction costs under construction grants** may generally include, but are not limited to, those listed below ([see also appendix 2](#)). Programmatic regulations and other terms of the award should be consulted for the specific costs allowable under a particular program.

- Allowable costs
  - Site survey and soil investigation
  - Site clearance (as long as reflected in bid)
  - Sidewalks necessary for use of facility
  - Driveways to connect with public roads
  - Parking areas
  - Bid advertising
  - Architect fees
  - Liability insurance
  - Fixed and movable equipment
  - Project management
  
  -
  
- Unallowable costs
  - Relocation of utilities
  - Offsite improvements
  - Consultant fees not related to actual construction
  - Equipment purchased through a conditional sales contract
  - Bonus payments to contractors
  - Damage judgment suits
  - Fundraising expenses
  - Legal services not related to site acquisition

**Consultant Services**--Allowable. A consultant is an individual hired to give professional advice or services for a fee but not as an employee of the hiring party. In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. In order to prevent apparent or actual conflicts of interest, grantees and third parties must establish written guidelines indicating the conditions under which the payment of consulting fees to employees is proper or improper. The term "consultant" also includes a firm that provides paid professional advice or services. Recipients are expected to have policies governing their use of consultants that are consistently applied regardless of the source of support and are expected to justify using consultants instead of salaried employees.

Charges to a project for consultant costs may include fees and travel costs (transportation/per diem/ subsistence costs). Under discretionary grants, PHS awarding office prior approval is required if the use of

consultants, either individuals or firms, constitutes a transfer of substantive programmatic work or is required by program regulations or other award terms. [See "Federal \(U.S. Government\) Employees"](#) for allowable costs associated with Federal employee consultants as well as circumstances of allow ability.

Consulting fees paid by an educational institution to a salaried member of its faculty are allowable only in unusual cases and only if both of the following conditions exist (see [Section J.6.e\(1\) of OMB Circular A-21](#)):

- The consultation is across departmental lines or involves a separate or remote operation.
- The work performed by the consultant is in addition to his or her regular departmental workload.

In all other cases, consulting fees paid to employees of recipient or contractor organizations in addition to salary may be charged to PHS grant-supported projects only in unusual situations and when all of the following conditions exist:

- The policies of the recipient or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received.
- The consulting services are clearly outside the scope of the individual's salaried employment.
- It would be inappropriate or not feasible to compensate the individual for these services through payment of additional salary.

Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be provided in writing on a case-by-case basis by the head of the recipient organization or contractor incurring the costs or his or her designated representative. If the designated representative is personally involved in the project or program under consideration, the authorization may be given only by the head of the recipient organization or contractor. This authorization must include determination that the required conditions are present and that there is no apparent or actual conflict of interest.

Recipients and contractors are encouraged to obtain written reports from consultants. If the recipient or contractor determines that a report is not feasible or would probably not be useful, it may exercise the option of not requiring a written report.

Where the costs of consultants are borne in whole or in part as direct costs by PHS projects, the consultation must be documented by an invoice from the consultant and a copy of the consultant's written report, if any. Any of the following information not shown on the invoice and/or report must be shown in a memorandum or other document, including handwritten notations on the invoice, signed by an organization official and retained in its files: the name of the consulting firm or individual consultants; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid, e.g., rate per day or hour worked or rate per unit of service rendered; and the amount paid.

**Consumer/Provider Board Participation**--Allowable in accordance with specific program regulations. When not specifically authorized by program regulations, only the following costs are allowable with the prior approval of the PHS awarding office:



- Reasonable and actual out-of-pocket costs incurred solely as a result of attending a scheduled meeting, including transportation, meals, babysitting fees, and lost wages.
- The reasonable costs of necessary meals furnished by the grantee to consumer or provider participants during scheduled meetings if not reimbursed to participants as per diem or otherwise.

Where programmatic regulations permit but establish a maximum annual income for eligibility for reimbursement of consumer/provider board members for wages lost by reason of their participation in board activities, the determination of eligibility will be made on the basis of gross rather than net income.

Members of consumer/provider boards are not considered employees or consultants of the grantee organization and therefore may not be compensated for their services other than as above nor are they eligible for associated fringe benefits. Although not eligible for individual insurance coverage, board members may be covered by an organizational insurance policy while acting in their official capacities as board members ([see "Insurance"](#)).

**Contingency Funds**--Contributions set aside for events whose occurrence cannot be foretold with certainty as to time, intensity, or assurance of their happening are unallowable under non-construction grants ([see appendix 2 concerning contingency funds under construction grants](#)). Contingency funds do not include pension funds, self-insurance funds, and normal accruals ([see also "Reserve Funds"](#)).

**Contracting Under Grants**--Allowable. [See section 8, "Procurement."](#)

**Customs and Import Duties**--Allowable. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges.

**Dependency Allowances (Fellowship and Training Programs)**-- Generally unallowable ([see "Trainee Costs"](#)).

**Depreciation or Use Charges**--Not normally allowable as a direct cost but may be included in the grantee's indirect cost pool. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowed.

**Donors Costs**--Allowable for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project related.

**Drugs**--Allowable. [See 42 CFR Part 50, Subpart E](#) for the maximum allowable cost for drugs under PHS grant-supported projects and activities for health services.

Project funds may not be used to purchase **drugs classified by the Food and Drug Administration** as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.

**Dues**--Allowable for organizational membership in professional organizations or societies if it can be shown that such membership is necessary to accomplish the objectives of the project. Such costs are not allowable under conference grants.

Payment of dues for an individual's membership in a professional organization is allowable as a fringe benefit or an employee development cost if paid according to an established institutional policy consistently applied regardless of the source of funds.

**Entertainment Costs**--Not allowable. This includes the cost of amusements, social activities, and related incidental costs.

**Equipment**--Allowable. For policies governing the use, management, and disposition of equipment, [see section 8, "Property Management and Accountability."](#) For policies governing the amount of allowable costs that may be charged for rental of equipment, [see "Rental or Lease of Facilities and Equipment."](#)

Conference grant funds may not be used for the purchase of equipment.

**Federal (U.S. Government) Employees**--The following rules apply to payments made to Federal employees under a PHS grant-supported project:

1. **Consultant fees:** Allowable only for medical personnel of the Uniformed Services of the United States (excluding Commissioned Officers of the Public Health Service) when all of the following conditions are present:
  - a. The employees are providing the kind and extent of medical services approved in the grant award.
  - b. Adequate numbers of qualified civilian medical personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available.
  - c. The eligible Federal medical personnel employed as consultants have prior written authorization from their commanding officers to the effect that they are authorized to work on the grant-supported activity and to be paid for their efforts. Such authorizations may be given when the work will be performed during nonduty hours or while employees are on authorized leave and the work will not interfere with the performance of their Federal duties.
2. **Outpatient or subject costs:** Allowable when the employee is a patient or subject undergoing study in connection with activities supported by the grant.
3. **Salary:** Temporary employees specifically hired to assist in the conduct of a sponsored PHS assistance program may, if authorized by the grant award, be reimbursed from grant funds. Except as provided in paragraphs a, b, and c below, no salary or fringe benefit payments may be made from PHS grant funds to career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided under existing position ceilings of a given Federal component.

These payments may be allowable when the employees obtain written prior approval from their PHS agency and the employee is--

- a. Either a Commissioned Officer of the Public Health Service or a civil service employee carrying out duties for which specific legislative authorization exists permitting direct Federal assistance in lieu

of cash under the grant or where the Government is reimbursed for services rendered subject to restrictions applicable to such personnel, including the Departmental Standards of Conduct.

- b. A Commissioned Officer of PHS on a leave-without-pay (LWOP) detail, provided--
  - (1) The grantee has obtained written prior approval from the PHS awarding office.
  - (2) The total amount of salary paid from PHS grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances officers would receive from PHS if they were not on LWOP detail.
  - (3) The parties concerned have made a prior determination that there is no actual or apparent conflict of interest or other violations of the Departmental Standards of Conduct.
- c. A civil service employee--
  - (1) Working under a grant to a non-Federal institution, in which case salary payments from PHS grant funds must be proportional to the time an individual devotes to the project. The total salary support may not exceed the normal level of compensation for the work performed.
  - (2) Performing services other than consultant services, during nonduty hours, while in LWOP status, or on detail to a State or local government, educational institution, or other nonprofit organization provided--
    - (a) Prior written approval is obtained from the PHS grant awarding office.
    - (b) All parties concerned are assured that there is no possibility of dual compensation for the same work or an actual or apparent conflict of interest or other violation of the Departmental Standards of Conduct. The grantee/applicant must submit a letter from a supervisory or personnel official in the Federal employee's employing agency which approves his working on the grant project. Such documentation must be provided to and deemed acceptable by the GMO of the awarding office prior to incurring any cost chargeable to the grant project for that employee's services.

#### 4. Travel: Allowable when the employee is--

- a. Working under a grant to a Federal institution.
- b. Performing allowable reimbursable services as outlined above.
- c. Attending a PHS grant-supported conference during nonduty hours; while in a preexisting LWOP status or one which continues beyond the conference; or on detail to a State or local government, educational institution, or other nonprofit organization, provided such payments are made in accordance with established institutional policy and the parties concerned have taken care to ensure that there is no actual or apparent conflict of interest.
- d. Commissioned Corps personnel satisfying requirements 3.b.(1) and (3) above.

The four types of costs listed above are the only costs that can be charged to PHS grants on behalf of Federal employees. Recipients should advise any Federal employees with whom these types of arrangements may be made to consult with their employing agency concerning the allow ability of such payments.

The above limitations do not apply to individuals who are part-time Federal employees because of service on advisory groups or as consultants to Federal agencies. (See HHS Standards of Conduct Regulations in 45 CFR Part 73, Subpart J, for additional guidance.)

**Fines and Penalties**--Allowable only when resulting from violations of, or failure of the organization to comply with, Federal, State, and local laws and regulations when incurred as a result of compliance with specific provisions of an award or instructions in writing from the awarding office.

**Fringe Benefits**--Allowable in proportion to the amount of time or effort employees devote to the grant-supported project provided such costs are incurred under formally established and consistently applied policies of the organization (see "Salaries and Wages").

**Tuition or tuition remission** for regular employees or their families is allowable as a fringe benefit. For policies applicable to tuition remission for students working on grant-supported projects, see "Salaries and Wages." See "Trainee Costs" for the allow ability of tuition costs for trainees and fellows.

**Fundraising**--Not allowable.

**Honoraria**--Not allowable when the primary intent is to confer distinction on or to symbolize respect, esteem, or admiration for the recipient. An honorarium that constitutes a payment for services rendered, such as a speaker's fee under a conference grant, is allowable.

**Hospitalization**--See "Patient Care."

**Insurance**--Allowable. Insurance is usually treated as an indirect cost. In certain situations, however, where special insurance is required because of risks peculiar to the project, the premium may be charged as a direct cost if consistent with organizational policy. Such premiums may include those on hazard, malpractice, and other liability insurance to cover the grant-supported project and the approved activities of grant-supported personnel, including trainees, fellows, and governing board members.

**Costs of insuring equipment purchased with project funds** should normally be included in indirect costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Cost of insurance on Federal Government-owned equipment is allowable.

**The cost of medical insurance for fellows and trainees** is allowable as part of the institutional allowance (see "Trainee Costs") if such medical insurance is required of all students of similar standing as a condition of the individual's participation in the institution's programs, regardless of the source of support.

**Interest**--Not allowable, unless specifically provided for under program legislation such as that authorizing the payment of interest on loans for the acquisition and/or modernization of existing buildings or allowable under the applicable cost principles.

**Land or Building Acquisition**--Not allowable unless acquisition or construction is specifically authorized by program legislation and provided for in the grant award. Under those PHS programs that have authority to permit recipients to acquire facilities, considerations such as the type of program(s) being supported and the Federal interest in purchased property will be taken into account by the PHS awarding office in determining whether property should be leased or purchased ([see "Rental or Lease of Facilities and Equipment"](#)). For real property acquired with grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees incurred with the recordation in appropriate official records of the applicable jurisdiction of the Federal interest in the real property may also be charged to the grant. Use allowance or depreciation on buildings which were not acquired under a Federal project are allowable, usually as an indirect cost. (See also "Facilities Purchased or Constructed by State or Local Governments.")

**Leave**--Allowable for employees as an employee fringe benefit ([see "Fringe Benefits"](#)). Although trainees and fellows in academic institutions are not entitled to vacations as such, they are entitled to normal student holidays and the period between semesters observed by their training institutions. Trainees and fellows in nonacademic institutions are entitled to the holiday and vacation schedule applicable to all trainees and fellows at the institution.

**Legal Services**--Allowable where required in the administration of a grant-supported project, subject to the limitations described below and the applicable cost principles.

**Legal costs incurred in the prosecution of claims**, whether equitable or monetary, against the Federal Government are unallowable charges to PHS grant-supported projects. However, the legal costs of pursuing an administrative action, e.g., an administrative grant appeal, are allowable.

**Before the recipient incurs legal costs** that are extraordinary or unusual in nature, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the appropriate GMO of the PHS awarding office.

**Library and Information Services**--Allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity--for example, in those programs designed to develop and support such services. General library support is not allowable as a direct cost but may be included in the recipient's indirect cost pool.

**Lobbying**--Generally unallowable. Costs of lobbying activities to influence legislative action pending before the U.S. Congress are unallowable. Costs of lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement are unallowable.

If the recipient organization believes that the **lobbying costs are necessary to carry out the project**, it must obtain an advance understanding with the GMO of the PHS awarding office. ([See also section 4, "Public Policy Requirements, Lobbying."](#))

**Meals**--Allowable for subjects and patients under study when an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement, as part of a per diem or subsistence allowance provided in conjunction with allowable travel, or when meals are a necessary and integral part of a conference being supported by a conference grant, provided that

such charges are not duplicated in participants' per diem or subsistence allowances. Guest meals are not allowable. ([See "Consumer/Provider Board Participation"](#) regarding the allow ability of cost of meals for consumer and provider board participants in grant-supported activities.)

**Moving**--[See "Recruitment," "Relocation," and "Transportation of Property."](#)

**Motion Pictures**--[See "Audiovisual Activities."](#)

**Nursery Items**--Allowable for purchase of toys, games, etc. to allow patients to attend clinic sessions or for diagnostic or therapeutic purposes in child development clinics and similar programs.

**Overtime**--[See "Salaries and Wages."](#)

**Patient Care**--Allowable to provide routine and ancillary medical services on either an inpatient or outpatient basis if the recipient has obtained prior approval from PHS to treat patients and to incur patient care costs in the project receiving grant support. Patient care costs where the need to incur such costs has not previously been approved by PHS and re-budgeting out of patient care costs must have PHS prior approval.

The following otherwise **allowable costs are not classified as patient care costs**: items for personal expense reimbursement, such as patient travel; consulting physician fees; or any other direct payments to patients, including inpatients, outpatients, subjects, volunteers, and donors. Such costs are considered to be in the "Other Expenses" category of the budget.

For **research grants**, the institution will be reimbursed on the basis of research patient care costs expressed as a rate or amount.

For **grants other than research grants**, reimbursement will be made on the basis of "reasonable cost" as set forth in the Principles of Reimbursement for Provider Costs (under Title XVIII of the Social Security Act) published by the Health Care Financing Administration, HHS, except where a different basis for reimbursement is set forth in governing programmatic regulations or guidelines ([see Cost Principles for Hospitals, 45 CFR Part 74, Appendix E](#)).

**Pension Plan Costs**--Allowable if the benefits are reasonable and are provided according to the established policies of the organization consistently applied regardless of the source of funds, the amount assigned to each fiscal year is in accordance with generally accepted accounting principles, and the cost assigned to a given fiscal year is paid or funded for all plan participants within 6 months after the end of that fiscal year. Amounts funded in excess of the pension costs assigned to a given fiscal year shall be applied to future years.

"**Pension plan**" is defined as a plan established and maintained by an employer to systematically provide for the payment of benefits to its employees after their retirement and may also provide benefits such as permanent and total disability or survivorship payments to beneficiaries of deceased employees. The "pay-as-you-go" cost method, i.e., when pension benefits are paid by a recipient directly to, or on behalf of, retired former employees or their beneficiaries, may be used by State, local, or Indian tribal governments or hospitals. Under this method, the benefits may be charged in the year in which the payments are made to,

or on behalf of, retired former employees or their beneficiaries, provided that the recipient follows a consistent policy of treating such payments as expenses in the year of payments. See the applicable cost principles for additional information on the allow ability of costs associated with pension plans.

**Pre-award (Pre-agreement)**--A grantee may, at its own risk, incur obligations and expenditures to cover costs prior to the effective date of an award provided the following criteria are met: the costs concerned are considered necessary to the conduct of the project, the costs are allowable under the potential award, and when required for specific expenditures or activities, PHS prior approval was obtained. For new and competing continuation awards, the costs must be incurred within 90 days prior to the effective date of the award. In allowing the applicant/grantee this flexibility, PHS expects the grantee to be fully aware that such borrowing against future support must not impair its ability to accomplish the project objectives in the approved timeframe or in any way adversely affect the conduct of the project. Additionally, the incurrence of costs prior to the award of a grant imposes no obligation on the Federal Government to either make the award or increase the amount of the approved budget.

**Public Information Services**--Allowable.

**Publications**--Allowable.

Page charges for publication in professional journals may be paid from project funds if both of the following conditions are met:

- The paper reports work supported by the grant.
- The charges are levied impartially on all papers published by the journal, whether or not by Government-sponsored authors.

**Other publication costs** such as publications, books, monographs, and pamphlets are allowable. The cost of a single publication not exceeding \$25,000 may be approved by the grantee institution. Costs exceeding \$25,000 for a single publication must receive prior approval from the PHS awarding office. Purchase of reprints without covers is an allowable cost. Purchase of reprints with covers is allowable only if the cost is the same as without covers or where the publisher sells only reprints with covers.

**Publications, journal articles, etc.**, produced under a PHS grant-supported project must bear an acknowledgment and disclaimer, as appropriate, such as:

This publication (journal article, etc.) was supported by Grant No. \_\_\_\_\_ from (name of awarding agency). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of (name of awarding agency). [See also section 8, "Publications."](#)

**Recruitment**--Allowable subject to the conditions and restrictions contained in the applicable cost principles. These costs may include help-wanted advertising costs, travel costs to pre-employment interviews incurred by applicants, and travel costs of employees while engaged in recruiting personnel. Project funds may not be used for a prospective trainee's travel costs to or from the grantee institution for the purpose of recruitment. However, other costs incurred in connection with recruitment under training or manpower programs, e.g., advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles concerning recruitment costs ([see "Travel"](#) and ["Relocation"](#)).



**Registration Fees (for Symposiums and Seminars)**-- Allowable if necessary to accomplish project or program objectives.

**Relocation**--Allowable in other than change of grantee institution situations when such costs are incurred incident to the permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project or upon recruitment of a new employee for work on the project, provided that the move is for the benefit of the grantee organization and payment is made according to established organization policies consistently applied regardless of the source of funds. These costs may include transportation of the employee, his or her family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home (see OMB Circular A-122). Where relocation costs have been incurred in connection with the recruitment of a new employee and the employee resigns for reasons within his control within 12 months after hire, the institution must credit the grant account for the full cost of the relocation charged to the grant.

In **change of grantee institution** situations, the personal relocation expenses of project directors or principal investigators and others moving from the original grantee to a replacement grantee ([see section 8, "Changes in Project"](#)) are not allowable charges to PHS grants.

**Rental or Lease of Facilities and Equipment**--Allowable as indicated below. Due to the complex nature of determining the allowable amount under certain types of leases, grantees are encouraged to consult the PHS awarding office GMO before entering into leases that will result in direct charges to the grant project.

In general, the **rental costs for facilities and equipment** applicable to each budget period should be charged to that period as specified on the NGA. However, [see section 8, "Procurement,"](#) for an exception to this general rule.

Subject to the limitations below, rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease, in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives.

**Rental costs under leases** that create a material equity [\(5\)](#) in the leased property are allowable only up to the amount that would be allowed under the applicable cost principles had the lessee purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, insurance, etc., but would exclude unallowable costs. A lease giving rise to material equity would be one that is non-cancelable or is only cancelable upon the occurrence of some remote contingency and has one or more of the following characteristics:

- The lessee has the right to purchase the property for a price that at the beginning of the lease appears to be substantially less than the probable fair market value when it is permitted to purchase the property (commonly called a lease with a bargain purchase option.)
- Title to the property passes to the lessee at some time during or after the lease period.



- The term of the lease (initial term plus periods covered by bargain renewal options, if any) is equal to 75 percent or more of the economic life of the property, i.e., the period the property is expected to be economically usable by one or more users.

When an **institution transfers property** to a third party through sale, lease, or otherwise and then leases the property back from that third party, the lease cost that may be charged to PHS projects generally may not exceed the equivalent of the cost of ownership.

**Rental costs under less-than-arms-length leases** are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the lessee. Under such leases, one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include but are not limited to those between divisions of an organization; organizations under common control through common officers, directors, or members; and an organization and a director, trustee, officer, or key employee of the organization, or his or her family, either directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.

**Reserve Funds**--Allowable for specific programmatic purposes only where permitted by a program's authorizing statute or governing regulations.

**Contributions to a reserve fund for self-insurance** are allowable as specified in the governing cost principles ([see "Contingency Funds"](#)).

**Sabbatical Leave**--Sabbatical leave costs may be included in a fringe benefit rate or in the institution's indirect cost rate. Salary may be charged directly to a project for services rendered the project by individuals while they are on sabbatical leave provided that the salary is proportional to the service rendered and is paid according to established institutional policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from a PHS grant), may not exceed 100 percent of individuals' regular salary from their institution.

**Salaries and Wages**--Allowable. Compensation for personal services covers all amounts paid or accrued by the organization for services rendered to the project. These costs are allowable to the extent that they are reasonable and conform to the established, consistently applied policy of the organization and reflect no more than the percentage of time actually devoted to the PHS-funded project.

- **Payroll distribution:** Amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system. Standards for payroll distribution systems are contained in the applicable cost principles. Briefly summarized, these approved systems are as follows:

1. Hospitals

- a. Monthly after-the-fact reports of the distribution of time or effort for professional staff.
- b. Time and attendance and payroll distribution records for nonprofessional employees.

2. Nonprofit organizations

- a. Monthly after-the-fact reports, including a signed certification by the employee or a responsible supervisory official having firsthand knowledge of the work performed that the distribution of activity represents a reasonable estimate of the actual work performed by the employee during the periods covered by the reports. Each report must account for the total activity for which employees are compensated and which is required in fulfillment of their obligations to the organization.
- b. For nonprofessional employees, additional supporting reports indicating the total number of hours worked each day must be maintained in conformance with the Department of Labor regulations implementing the Fair Labor Standards Act (29 CFR Part 516).

The distribution of salaries and wages must be supported by personnel activity reports as described above, except when a substitute system has been approved in writing by the cognizant agency designated under OMB Circular A-122.

### 3. State, local, and Indian tribal government agencies

- a. Time and attendance or equivalent records for all employees.
- b. Time distribution records for employees whose compensation is chargeable to more than one grant or other cost objective.

### 4. Educational institutions

- a. A plan confirmation system for professorial or professional staff based on budgeted, planned, or assigned work activity, updated to reflect any significant changes in work distribution.
- b. Activity records system reflecting an after-the-fact reporting of the percentage distribution of activity of employees. For professorial and professional staff, the reports will be prepared each academic term, but no less frequently than every 6 months. For other employees, unless alternative arrangements are agreed to, the reports will be prepared no less frequently than monthly and will coincide with one or more pay periods.
- c. Multiple confirmation records system for professorial and professional staff, prepared each academic term, but no less frequently than every 6 months.
- d. By mutual agreement, any other method meeting the criteria specified in paragraph J.6.b.(2) of OMB Circular A-21.

Charges for work performed by faculty members on sponsored research projects during the summer months or other period not included in the base salary period will be determined for each faculty member at a rate not exceeding the base salary divided by the period to which the base salary relates. The base salary period used in computing charges for work performed during the summer months will be the number of months covered by the faculty member's official academic year appointment.

- ***Alternate use of salary support due to receipt of a Research (Career Scientist) Development Award:*** Grant funds awarded under a PHS grant for an individual's salary but which are no longer required for that purpose as the result of the transfer of that individual's salary to a Research Career Development Award (RCDA) or other RCDA-type career development award may not be used for any other purpose without written prior approval from PHS.
- ***Overtime premiums:*** Premiums for overtime are generally allowable (see governing cost principles); however, such payments are not allowable for faculty members at institutions

of higher education. Where overtime premiums are allowable, the categories or classifications of employees that are eligible to receive overtime premiums should be determined according to the formal policies of the organization consistently applied regardless of the source of funds.

- ***Bonus payments:*** Allowable as part of a total compensation package provided that such payments are reasonable and are made according to a formal policy of the recipient organization that is consistently applied.
- ***Support from multiple grants:*** See section 8, "Prior Approval Authorities, Closely Related Work."
- ***Compensation of students:*** Tuition remission and other forms of compensation paid as, or in lieu of, wages to students (including fellows and trainees) performing necessary work are allowable provided that there is a bona fide employer-employee relationship between the student and the institution for the work performed, the tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work, and it is the institution's practice to similarly compensate students in non-sponsored as well as sponsored activities. However, payments made for educational assistance (i.e., scholarships, fellowships, and student aid costs) may not be paid from PHS research grant funds even when they could appear to benefit the research project to some degree. Also, see section 4, "Public Policy Requirements, Student Unrest Provisions."

The determination as to the allow ability of such compensation as a charge to a grant will be made on the basis of the cost principles without regard to whether the compensation is or is not taxable. Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages shall be subject to the reporting requirements in section J.6 of OMB Circular A-21 and shall be treated as direct or indirect costs according to the actual work being performed. Tuition remission may be charged on an average rate basis.

- ***College Work Study Program:*** PHS grant funds may be used to pay all or part of the non-Federal share of a student's compensation under the Department of Education's College Work Study Program. Payment of such compensation must be for the performance of services necessary to the approved project from which payment is made.

***Service Charges***--The costs of institutional services and central facilities owned by the recipient institution, such as computer services, are allowable.

***Severance Pay***--Allowable only to the extent that such payments are required by law, employer-employee agreement, established policy that constitutes an implied agreement on the part of the organization, or the circumstances of the particular employment. The amount of severance pay to be provided should be determined according to the established organizational policy consistently applied regardless of the source of funds and should be reasonable, taking into consideration the practice of similar types of organizations and the extent of the organization's dependence on

Federal funds. The applicable cost principles should be consulted regarding the different treatment of severance pay in regular and mass termination situations.

***Subject Costs***--See "Patient Care."

***Supplies***--Allowable.

***Taxes***--Allowable. Such costs include taxes that an institution is required to pay as they relate to employment, services, travel, renting, or purchasing for a project. Institutions must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. On projects involving construction, State sales and use taxes for materials and equipment are allowable only when no refund or exemption on such taxes is granted by the State.

***Termination Settlements***--When a grant is terminated, the grantee shall not incur new obligations for the terminated portion after the effective date and shall cancel as many outstanding obligations as possible. The granting agency shall allow full credit to the grantee for the Federal share of the non-cancelable obligations properly incurred by the grantee prior to termination. See 45 CFR Parts 74.115(c) and 92.43. Costs related to the sale of property are not allowable if the grantee is reimbursed at a fixed amount or rate according to 45 CFR Part 74, Subpart O, or 45 CFR Part 92.31.

***Trailers and Modular Units***--Allowable as indicated below. A "trailer" is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A "modular unit" is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to PHS grant-supported projects depends on whether such units are classified as real property or as equipment. The classification will depend on whether the recipient's intended use of the property is permanent or temporary.

A **trailer or modular** unit would be considered as real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to a PHS grant-supported project unless authorizing legislation permits construction or acquisition costs or purchase of real property and the specific purchase is approved by the PHS awarding office.

A trailer or modular unit would be considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to PHS grant-supported projects only if program regulations do not prohibit the purchase of equipment and prior approval is obtained as appropriate.

A trailer or modular unit properly classified as real property or equipment at the time of acquisition shall retain that classification for the life of the item, thereby determining the appropriate accountability requirements under 45 CFR Part 74, Subpart O, or 45 CFR Parts 92.31 and 92.32.

**Trainee Costs**--Allowable under pre-doctoral and postdoctoral training grants if permitted by the authorizing statute or governing programmatic regulations. For each individual to be trained, such costs may include a stipend and tuition and fees, including the costs of medical insurance required of trainees as a condition of their participation in the organization's training program and required of all students of similar standing, regardless of the source of funding, which are directly associated with and necessary to the individual's training and are incurred within the period of grant-supported training. Grantee institutions may re-budget funds into or within the trainee cost category (i.e., stipends, tuition, and fees, including medical insurance) but may not re-budget funds awarded for trainee costs into another budget category without PHS awarding office prior approval. Trainee travel is *not* considered a trainee cost for the purposes of re-budgeting. Funds may be re-budgeted into trainee costs without PHS prior approval to the extent that the resulting support for trainees does not constitute a change in the scope or objectives of the approved project (see section 8, "Changes in Expenditures/Activities").

- **Dependency allowances:** Generally not allowable.
- **Institutional allowances (Fellowships) and training-related expenses (Training Grants):** Institutional allowances may be requested by institutions sponsoring a pre-doctoral or postdoctoral fellow unless otherwise restricted by law or regulations.

For training grants awarded under the National Research Service Award authority, training-related expenses are also based on certain allowable ceiling (maximum) amounts per year for each full-time pre-doctoral and postdoctoral trainee.

Applicants for training grants and individual fellowships should consult the individual program announcement or application kit for the applicable institutional allowances provided under a particular program. Institutional allowances under fellowships are provided in lieu of all other institutional costs and are intended to cover expenses including the following: tuition and fees, including the costs of medical insurance, required of fellows as a condition of their participation in the organization's training program and required of all students of similar standing, regardless of the source of funding; supplies and equipment; faculty salary; trainee travel to attend scientific meetings; and other administrative costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs, such as those incurred when the training requires field research and/or travel to foreign sites. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution.

Expenditures under *fellowship institutional allowances* are not subject to PHS prior approval and re-budgeting requirements nor is the sponsoring institution required to account for these expenditures on an actual cost basis. However, if the fellow is not enrolled or engaged in training for more than 6 months of the year of support for which the award was made, only one-half of that year's allowance may be charged to the grant.

Institutional costs under training grants, e.g., research supplies and equipment and faculty salaries, are allowable in accordance with the rules on cost allow ability prescribed in the cost principles and this section.

- **Stipends:** Allowable for fellowships, training grants, or other types of grant-supported projects where such payments are specifically permitted under the governing legislation or program regulations.

Stipends provided to individual fellows or trainees are paid in accordance with pre-established levels. Stipend levels for full-time PHS fellowships and traineeships are based on a support year of 12 months. See the individual program announcement or application kit for information on relevant stipend levels.

An institution is allowed to provide funds to an individual in addition to the stipends paid by PHS. Such additional amounts may either be in the form of augmented stipends, i.e., "supplementation," provided without obligation to the fellow or trainee according to institutional policy or in the form of compensation (salary and/or tuition remission) for services such as teaching or serving as a laboratory assistant. However, funds characterized as "compensation of students" that meet the requirements under "Salaries and Wages, Compensation of students" are not considered stipend supplementation. Also, assistance under the Veterans Readjustment Benefits Act (G.I. Bill) is not considered as supplementation. Under no circumstances, however, should the service requirements detract from or prolong the training.

Institutions can determine what amount of supplementation, if any, will be provided according to their own formally established policies governing supplementation. The institution's policies on supplementation must also include a means to ensure that those policies are followed consistently. The policies must be documented and are subject to audit. No Federal (grant) funds may be used for supplementation unless specifically authorized under the terms of both the program from which such supplemental funds are to be received and the program whose funds are to be supplemented. This is not intended to discourage the use of Federal loan funds.

- **Travel:** Costs associated with travel necessary to an individual's training, including attendance at meetings, that are incurred within the period of grant-supported training are allowable under PHS training grants. Registration fees associated with such meetings are also allowable. However, travel costs may not include travel between the trainee's or fellow's place of residence and the training site, except in the case of certain specialized programs that are relatively short in duration and are expressly designed to train specific disadvantaged beneficiaries or in the case of extreme need or hardship of an individual trainee or fellow where a one-way travel allowance may be authorized by the grantee. In the case of individual fellowships, such travel will be paid from the institutional allowance (see "Trainee Costs, Institutional allowances"). Awards for training at a foreign site may include a single round-trip economy or coach fare.
- **Tuition and related costs:** Allowable unless otherwise provided by the terms and conditions of the award. Tuition and fees are allowable only to the extent that the same resident or nonresident tuition and fees are charged to regular non-federally supported students. Tuition at the postdoctoral level is limited to that required for specified courses.

***Transportation of Property***--Allowable for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, including instances when equipment or other property is moved from one recipient organization to another. In a change of grantee institution situation, the cost of transportation may be charged to the grant at either the original or the new organization, depending on the circumstances and the availability of funds in the appropriate active grant account (see section 8, "Changes in Project").

***Travel***--Allowable as a direct cost where such travel will provide direct benefit to the project. According to the organization's established travel policy, such costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses such as mileage allowances if travel is by personal automobile.

Domestic travel is that performed within the recipient's own country. Domestic travel includes travel within and between any of the 50 States of the United States and its possessions and territories and also includes travel between the United States and Canada and within Canada.

Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country.

In all cases, travel costs are limited to that allowed by formal organizational travel policy and, in the case of air travel, less than first class accommodations must be used when available. Grantees are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets where travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipient institutions must comply with the requirement that U.S. flag air carriers be used by domestic grantees to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference.

If the recipient organization has no formal travel policy, HHS travel regulations, including maximum per diem and subsistence rates prescribed in those regulations, shall be used to determine the amount for travel costs. This information may be requested from the PHS awarding office and is available in the HHS Travel Manual for public inspection and copying at HHS and regional office information centers.

In addition to these general policies, some specific policies applicable to various types of travel and travelers are indicated below. Applicants and grantees should consult application instructions to determine how to budget for the following types of costs, since they are not all required to be budgeted as "travel."

- ***Patients:*** If patient care is an approved activity of the grant-supported project or program, the costs of transporting patients to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose may be allowable.

- **Conference Grants:** Per diem or subsistence allowances must be reasonable and must be limited to the days of attendance at the conference plus the actual travel time required reaching the conference location by the most direct route available. Where meals and/or lodgings are furnished without charge or at a nominal cost, e.g., as part of the registration fee, this should be taken into account in setting the per diem or subsistence allowance.

Travel costs for attendees and participants at the conference may not exceed economy class fare. In addition, the allow ability of foreign travel being supported by a conference grant (as proposed in the grant application) will be determined in accordance with PHS foreign travel restrictions in effect at the time of the award.

Conference grant funds may not be used to pay per diem or travel expenses other than local mileage for local participants in the conference.

## **INDIRECT COSTS**

In theory, all costs might be charged directly to benefiting projects or programs. However, most organizations incur allowable costs which cannot be readily identified with an individual project or program. In these situations, the costs are allocated to the projects and programs as "indirect costs." The end product of this allocation process is an indirect cost rate(s) which is then applied to individual grant-supported projects to determine the amount of its indirect costs.

The establishment of an indirect cost rate is not necessary if the organization's awards do not provide reimbursement for indirect costs or limit such reimbursement to 8 percent of direct costs as discussed below, the organization's total operations consist of a single grant-supported project, or the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project (see section 8, "Financial Management and Non-Federal Audits"). Such an accounting system must identify and segregate costs based on a process that assigns costs commensurate with the benefits provided to individual projects.

PHS reimbursement for indirect costs is subject to the following provisions:

1. Indirect costs under all training grants (6) other than those awarded to State or local government agencies will be reimbursed at 8 percent of total allowable direct costs exclusive of tuition and related fees and expenditures for equipment or at the actual indirect cost rate, whichever results in a lesser dollar amount. This limitation also applies to training funds provided under sub grants to organizations other than State or local government agencies. State and local government agencies will receive reimbursement at their full indirect cost rate for training grants.
2. Indirect costs on Research (Career) Development Awards will be reimbursed at 8 percent of total allowable direct costs, excluding the items in 1 above, or at the actual indirect cost rate, whichever results in a lesser dollar amount.



3. Indirect costs will not be paid on fellowships or similar awards where PHS funding is in the form of fixed amounts or the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
4. Indirect costs will not be reimbursed on construction grants.
5. Indirect costs will not be reimbursed on grants to individuals, foreign institutions, and Federal Government grantees.
6. Indirect costs for grants in support of conferences will not be allowed except in the most unusual circumstances and then only after negotiation (in advance of the award) between the applicant and the GMO of the PHS awarding office.
7. Grants on which indirect costs are limited or prohibited by law or regulation will be awarded in accordance with the legal or regulatory restrictions.
8. When the grantee waives reimbursement of full indirect costs, either no indirect costs or only partial indirect costs will be awarded as appropriate.
9. The total amount awarded by PHS (direct plus indirect) shall be based on the most current indirect cost rate at the time of award and shall constitute a ceiling on the amount payable to the grantee for a grant. The award of a grant shall not obligate PHS to make any supplemental or other award for additional indirect costs or for any other purpose.
10. If PHS funds are available, GMOs shall amend the grant to provide additional funds for indirect costs only in the following and in no other cases:
  - a. An error made by the granting agency in computing the award. Included in this exception is the proviso that the granting agency shall revise the award to provide additional funds for indirect costs when a higher rate(s) than the rate(s) used in the grant award is negotiated and becomes effective (that is, the date of the Indirect Cost Rate Agreement) on or before 1 calendar month prior to the beginning date of the grant budget period.
  - b. Restoration of funds previously recaptured by PHS as part of a grantee's unobligated balance.
  - c. New or delinquent grantees for which valid indirect cost rates are established subsequent to an award.
  - d. Indirect costs associated with any additional direct costs awarded for the expansion or extension of a project. Additional direct costs awarded for other reasons may be accompanied by associated indirect costs at the granting agency's option.
11. When a currently effective indirect cost rate is not available at the time of an award because the grantee was delinquent in the submission of its indirect cost proposal, the award shall not include funds for the reimbursement of indirect costs. If the grantee subsequently

establishes a currently effective rate, the GMO may exercise discretion to amend the award to provide an appropriate amount for indirect costs if the amendment can be made within the same Federal fiscal year in which the initial award was made. However, the amount will be limited to the indirect costs applicable to the period after the date of the grantee's application. This provision does not affect local government agencies that are not required to submit their indirect cost proposals to the Federal Government. They may charge indirect costs to HHS grants based on the rate computations they have prepared and are keeping on file for subsequent Federal review.

12. Grantees may re-budget between direct and indirect costs (in either direction) without PHS prior approval. However, this authority may be exercised for training grants awarded to institutions of higher education, hospitals, and other nonprofit institutions only when the institution's actual indirect cost rate applied to these grants is less than 8 percent of total direct costs as adjusted.
13. Reimbursement of indirect costs is based on the application of the appropriate indirect cost rate in effect during the period in which the allowable and allocable direct costs are incurred. The dollar amount of indirect costs applicable to a PHS grant-supported project shall be determined by multiplying the appropriate indirect cost rate(s) by the allowable direct costs that are actually incurred during that period.

Indirect cost proposals will be prepared in accordance with applicable cost principles and will conform to other cost policies in this policy statement. Guidance on the preparation of indirect cost proposals is provided in the following informational brochures, which may be obtained from the office negotiating the indirect cost rates (see appendix 8):

A Guide for Colleges and Universities (OASC-1, Revised)

A Guide for Hospitals (OASC-3, Revised)

A Guide for Nonprofit Institutions (OASMB-5, Revised)

A Guide for State and Local Government Agencies (OASC-10)

Grantees that use microcomputer-based automatic data processing systems to prepare indirect cost proposals, supporting schedules, etc., must be prepared to loan to HHS copies of the electronic media on which the proposal data are stored (e.g., computer disks), plus the operating application software and associated user documentation used to analyze and manipulate the data. Materials on loan to HHS will be used solely for review and analysis of the proposal and will be returned to the grantee after the indirect cost rates are negotiated. When grantees obtain proprietary software packages designed or intended to be used for making indirect cost proposal preparation, they must make sure that the terms of the acquisition (or other arrangement with the software vendor) permit loaning it to HHS.

Further information concerning the establishment of indirect cost rates and the reimbursement of indirect costs may be obtained from the offices that negotiate indirect cost rates (see appendix 8).

## **COST TRANSFERS**

Transfers of costs to PHS grants by grantees, sub grantees, and contractors under grants that represent corrections of clerical or bookkeeping errors must be made promptly after the error is discovered. The transfers must be supported by documentation that contains a full explanation of how the error occurred and a certification of the correctness of the new charge by a responsible financial or administrative official of the recipient organization. An explanation which merely states that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. It should be noted that frequent errors in the recording of costs may indicate the need for improvements in the grantee's accounting system and/or internal controls. Therefore, where such errors occur, grantees are encouraged and may be required to evaluate the need for improvements in these areas and to make what improvements are deemed necessary.

As stated in the applicable cost principles, transfers of costs from one budget period to the next solely to cover cost overruns is not allowable.

Health professions capitation grants are not subject to the policy stated above because of the general support nature of these awards and the latitude and flexibility allowed recipients in the use of these funds.

Documentation of cost transfers by grantees must be maintained and be made available for audit or other review pursuant to 45 CFR 74, Subpart D, and 45 CFR Part 92.42 (see section 8, "Record Retention and Access").

## **ALLOCATION OF COSTS WHEN WORK IS CLOSELY RELATED**

When salaries and/or other activities are being supported by two or more sources, issues arise as to how these costs should be allocated among the sources of support. It is HHS policy that if a cost benefits two or more projects or activities in proportions that can be determined, the cost should be allocated to the projects based on the proportional benefit. If a cost benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved, the costs may be allocated to benefited projects on any reasonable basis.

PHS has determined that when salaries and/or other activities are being supported by two or more PHS grant projects and the specific conditions given below are met, costs may be charged to any of those grants. Under these conditions, costs also may be assigned entirely to one project, with written prior approval from the PHS awarding office GMO. These conditions are as follows:

1. The projects are scientifically and technically related.
2. The projects are under the direction of the same principal investigator.
3. The projects have been funded by the same PHS awarding office.

4. There is no change in the scope of the individual grants involved.
5. The relating of costs will not be detrimental to the conduct of work approved under each individual award.
6. The relatedness will not be used to circumvent the terms and conditions of an individual award.

## **APPLICABLE CREDITS**

The term "applicable credits" refers to those receipt or negative expenditure types of transactions that operate to offset or reduce expensive items that are allowable to grant-supported projects and activities as direct or indirect costs. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments or overpayments or erroneous charges.

Applicable credits to direct charges made to PHS grants must be treated as an adjustment on the grantee's Financial Status Report, whether those credits accrue during or after the period of grant support. The PHS awarding office will notify the grantee of any additional actions that may be necessary (see section 8, "Reporting, Financial Status (Expenditure) Reports").

## **RESEARCH PATIENT CARE RATES**

A hospital that has not previously established research patient care rates with HHS must submit its initial research patient care proposal to the appropriate Division of Cost Allocation (DCA) Regional Administrative Support Center responsible for the HHS region in which the hospital is located immediately after being notified that a grant providing for the reimbursement of research patient care costs will be awarded. Hospitals that have previously established research patient care rates with the Department must submit a new research patient care rate proposal to DCA within 6 months after the close of each fiscal year. If a hospital is unable to submit a proposal by the prescribed date, it may request an extension of time from DCA. This request must contain a justification for the extension and must specify the date the proposal will be submitted. The request should be submitted on or before the due date of the proposal. DCA will review the research patient care proposals submitted by the hospitals and, based on these reviews, will negotiate appropriate research patient care rates with them. The amount included in PHS grant awards for research patient care costs will be based on the research patient care rates established by the hospital with DCA.

The following requirements apply to hospitals that are awarded \$25,000 or less in research patient care costs under any single grant awarded by PHS:

1. If the hospital is a sub-awardee hospital, the grantee will be responsible for negotiating reasonable fees for research patient care services provided by the hospital.

2. If the hospital is a grantee, it must support its claims for the reimbursement of research patient care costs by preparing a research patient care rate computation for each fiscal year during which the costs are claimed. The computation must be based on Section IX.B.23 of the Department's cost principles for hospitals (45 CFR Part 74, Appendix E) and must conform to the proposal formats shown on pages 9 through 11 of *A Guide for Hospitals*. The computation, along with the supporting documentation described in the guide, must be retained by the hospital for possible review and audit by, or in behalf of, the Department. The retention period shall be in accordance with the Department's records retention regulations (45 CFR Part 74, Subpart D). The rates developed by the hospital will be treated as predetermined rates. However, the patient care costs reflected in the hospital's expenditure reports based on these rates will be subject to adjustment if an audit or other review by, or in behalf of, PHS results in a reduction in the rates.

### **SERVICES PROVIDED BY AFFILIATED INSTITUTIONS**

A number of universities and other institutions have established closely affiliated but separately incorporated institutions to facilitate the administration of research and other programs supported by Federal funds. Such legally independent institutions are often referred to as "foundations," although this term does not necessarily appear in the name of the institution. Typically, the parent institution provides considerable support services in the form of administration, facilities, equipment, accounting, etc., to its foundation, and the latter, acting in its own right as a PHS grantee, includes the cost of these services in its indirect cost proposal.

Costs incurred by an affiliated but separate legal entity in support of a grantee foundation are allowable for reimbursement under PHS grants only if one of the following conditions is met:

1. The grantee foundation performing under a PHS grant award is charged for, and is legally obligated to pay for, the services provided by the parent institution.
2. The affiliated institutions are subject to a State or local law that prescribes how Federal reimbursement for the costs of the parent institution's services will be expended and requires that a State or local official acting in his or her official capacity approves such expenditures.
3. There is a valid written agreement between the affiliated institutions whereby the parent institution agrees that the grantee foundation may retain Federal reimbursement of parent institution costs. The parent institution may either direct how the funds will be used or permit the grantee foundation that discretion.
4. The affiliated institutions submit joint applications for a PHS grant award, and the PHS grant award is made to them jointly.

If none of the above conditions is met, the costs of the services provided by the parent institution to the grantee foundation are not allowable for reimbursement. However, the services may be acceptable as third-party, in-kind contributions for matching purposes (see section 6).

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- (1)** *For certain re-budgeting actions, grantees must obtain any required prior approval in writing from the GMO. For sub grants and contracts awarded by grantees, the prior approval authority is usually the grantee. However, the grantee may not approve any action or cost which is inconsistent with the purpose or terms of the Federal grant. If an action by a sub grantee or contractor will result in a change in the overall grant project or budget requiring granting agency approval, the grantee shall obtain the approval from PHS before giving its approval to the sub grantee or contractor.*
- (2)** *All references to "contractors" in this section on costs under PHS grants refer to cost-type contractors.*
- (3)** *References to nonprofit organizations other than institutions of higher education and hospitals in this section apply to such nonprofit organizations covered by OMB Circular A-122, i.e., private nonprofit organizations. However, a few of the larger nonprofit organizations which are specifically listed in Attachment C to OMB Circular A-122 shall be subject to the Federal cost principles applicable to commercial firms (48 CFR Subpart 31.2) rather than to the cost principles for nonprofit organizations. Rules governing the allowability of bid and proposal costs and independent research and development costs for nonprofit organizations are in subparagraphs 74.174(b) and (c) of 45 CFR Part 74.*
- (4)** *This may be obtained from the Division of Research Resources, National Institutes of Health, Bethesda, MD 20892.*
- (5)** *The definition of "material equity lease" in this section differs from the definition of this term in the cost principles for educational institutions (OMB Circular A-21). For those institutions, the definition in A-21 shall govern.*
- (6)** *For this purpose, "training grant" means any grant (sub grant, contract) under which PHS financing is provided on a cost-reimbursement basis for all or an agreed upon portion of the costs incurred for training or other educational services. It does not include fellowships or similar awards where recipients are not required to account on an actual cash basis.*
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