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Mayo Clinic Rochester
200 First Street Southwest
Rochester, Minnesota 55905

To: Twila Martin Kekahbah

Date: February 8, 2000

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From: Judith S. Kaur, M.D.

Fax: 507-538-0823

Phone: 507-284-8318

Message:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health

National Cancer Institute
Executive Plaza South, Suite 320
9120 Executive Blvd., MSC 7161
Bethesda, Maryland 20892-7161
Telephone (301) 495-8588
FAX (301) 435-9225
e-mail: nci301@nih.gov

January 13, 2000

Judith S. Kaur, M.D.,
Mayo Foundation Rochester
Dept. of Oncology
200 First Street S.W.
Rochester, MN 55905

Dear Dr. Kaur:

Enclosed is a copy of the summary statement prepared by the scientific review administrator of the Initial Review Group (IRG) that evaluated your application. As part of this initial review process, reviewers identified those applications with the highest scientific merit for discussion and assignment of a priority score at the meeting.

Priority scores are the average of the scores assigned by each member of the IRG, based on their assessment of the application's scientific and technical merit. Reviewers were instructed to score applications that they determined to be in the top half of applications with a score between 1.0 and 3.0. Applications considered to be in the lower half were either assigned a score between 3.0 and 5.0 or were streamlined (not scored) or Not Recommended for Further Consideration (NRFC). The priority score is used to determine a percentile score, a measure of your grant's score compared to the others reviewed in the same study section. Since there can be significant differences in the rating behavior of different IRGs, NCI most often uses percentile ranking rather than priority scoring as the most important element in funding decisions. Like priority scores, a low percentile score is best.

At this time, no conclusions should be made concerning the probability of funding, since rank accorded your application by the IRG is only one of the factors that is considered in making funding decisions. Your application will complete the two-step evaluation process upon review by the National Cancer Advisory Board at its next meeting. If your application is selected for funding you will be contacted further by NCI staff. If your application is not selected for funding, it will then follow NIH procedures for administrative withdrawal and no further communication will be initiated by NCI regarding its status. This action will in no way affect any applications you may submit in the future.

If you have any concerns about the review of your application, I encourage you to discuss them with me as soon as possible.

Sincerely



Frank E. Jackson
Program Director

Enclosure

MR. FRANK E. JACKSON SUMMARY STATEMENT
 301 496-8589 OD CA INST (Privileged Communication)
 jacksonf@dcpcpn.nci.nih.gov

Application Number: 1 U01 CA86098-01

Review Group: ZCA1 SRRB-D (J1)
 NCI SPECIAL EMPHASIS PANEL

Meeting Dates: IRG: OCT/NOV 1999 COUNCIL: JAN/FEB 2000 43
 Requested Start Date: 03/01/2000
 CA99-003

KAUR, JUDITH S, MD
 MAYO FOUNDATION ROCHESTER
 DEPT OF ONCOLOGY
 200 FIRST STREET S W
 ROCHESTER, MN 55905

Project Title: THE AMERICAN INDIAN/ALASKA NATIVE INITIATIVE ON CANCER

IRG Action: Priority Score: 134
 Human Subjects: 30-HS INV-CERTIFIED NO IRG CONCERNS/COMMENTS
 Animal Subjects: 10-NO LIVE VERTEBRATE ANIMALS INVOLVED
 Gender: G1A-BOTH GENDERS, SCIENTIFICALLY ACCEPTABLE
 Minority: M1A-MINORITY & NON-MINORITY, SCIENTIFICALLY ACCEPTABLE
 Children: C1A-BOTH CHILDREN AND ADULTS, SCIENTIFICALLY ACCEPTABLE
 CLINICAL RESEARCH - NOT NIH-DEFINED PHASE III TRIAL

PROJECT YEAR	DIRECT COSTS REQUESTED	DIRECT COSTS RECOMMENDED	ESTIMATED TOTAL COST
01	1,085,711	1,085,711	1,282,520
02	1,201,335	1,201,335	1,419,103
03	1,209,282	1,209,282	1,428,490
04	1,194,118	1,194,118	1,410,578
05	<u>1,043,225</u>	<u>1,043,225</u>	<u>1,232,332</u>
TOTAL	5,733,671	5,733,671	6,773,023

NOTE TO APPLICANT FOLLOWS SUMMARY STATEMENT.

Administrative Comment

RESUME: This application was submitted in response to Request for Applications CA99-003, "SPECIAL POPULATIONS NETWORKS FOR CANCER AWARENESS RESEARCH AND TRAINING" by the Mayo Clinic. This application addresses a national health priority, and well documents the need for cancer awareness and cancer prevention among American Indians and Alaska Natives. It meets all the criteria set by the RFA, "Leadership Initiatives on Cancer." The application approaches the plan by a collaboration of partners to work toward minimizing mortality and morbidity, with a major goal of improving Native American community channels to NCI so that research can be focused on issues that affect the people in a culturally respectful way. The strength of the plan involves the participation of some of the major researchers in cancer research among American Indian/Alaska Native populations, national AI/AN organizations, and community organizations. The application is comprehensive and research design is well developed. There is an overall plan of process evaluation which will focus on assessments of the programs during the grant period and provide feedback to the collaborators for continuous improvement. This application was rated outstanding.

Date Released: 01/10/2000

Date Printed: 01/10/2000

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Judith S Kaur

DESCRIPTION: (Applicant's Description)

American Indian and Alaska Native (AI/AN) populations have very high incidence rates for specific cancer sites and poor survival rates for most cancers. This AI/AN Initiative on Cancer addresses comprehensive tribal cancer control through partnerships with The Network for Cancer Control Research among AI/AN Populations, tribes, multiple cancer centers, Cancer Information Services (CIS) and the American Cancer Society (ACS). This will assist tribes to 1) increase community awareness and understanding about cancer 2) provide training in cancer control research for AI/AN researchers, and 3) improve Native American community channels to NCI so that research can be specifically focused on issues that affect native people.

The specific aims to support these goals include:

1. Building infrastructure to support a nationwide AI/AN initiative
2. Increasing the number of AI/AN researchers, scientists, and medical students involved in cancer control activities in AI/AN communities
3. Developing, implementing, and assessing cancer education among AI/AN community members and their health care providers;
4. Strengthening collaborations of AI/AN communities with NCI, CIS, and ACS
5. Increasing the number of AI/AN patients in clinical trials (prevention, screening, treatment, and supportive care)
6. Providing feedback to the National Cancer Institute on community based priorities in the national cancer program These efforts should measurably increase awareness of the problem of cancer among AI/AN's and result in increased early detection of cancer. It may also increase the number of AI/AN patients seeking clinical trials.

The research methods include established successful cancer control training techniques through the Native Researchers Training Program, development of mini-grants to tribes, specific scope of work agreements with CIS, and coordination with ACS.

Collaborating Institutions: Fred Hutchinson Cancer Research Center, University of Arizona, Oregon Health Sciences University, University of Wisconsin Cancer Center, University of Alabama

CRITIQUE (This critique represents the edited review comments of individual reviewers. Thus, these comments may not be completely consistent with the overall merit rating resulting from the deliberations of the full review committee.)

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Judith S Kaur

Reviewer #1:

Significance:

The applications carefully follows the RFA requirements. The research data and literature demonstrates a great need for emphasis on cancer awareness and prevention among All AN with supporting up-to-date information. The data shows it is a significant health problem for this minority population as compared to the rest of the country. "For Native Americans, the 5 year survival rates for cancer is the worst among all racial groups and the disparity is increasing." The plan includes some of the leading cancer prevention experts in field. The lead roles include people who have heavy experience in the field working with Native American communities. The research plan has strength in that it draws upon existing networks, organizations, and initiatives to build it's own and a larger infrastructure to address the high cancer morbidity and mortality among this population. The goals and objectives are clearly stated with supporting specific aims to further describe how each plan will be carried out.

Approach:

The project will be carried out by 6 collaborating partners:

Mayo Clinic	in Rochester, Minnesota
Fred Hutchinson Cancer Research Center	in Seattle, Washington
University of Arizona	in Tucson, Arizona
Oregon Health Sciences University	in Portland, Oregon
University of Wisconsin Cancer Center	in Madison, WI
University of Alabama	in Birmingham, Alabama

The National Indian Health Board will also be a partner through a memorandum of agreement.

The conceptual framework and the research design are clearly stated, especially with visual art on how each entity (collaborating partners) will interrelate with one another to accomplish the goals and objectives (see figure on page 056). The plan is to draw upon existing smaller infrastructures to combine it's effort to strengthen strategy with cancer prevention activities with All AN communities. The participating partners have already a proven record in each of their own enterprise or effort. The biosketches of the investigator and the key personnel demonstrate lengthy experience in cancer prevention and work with All AN populations. Resources at the Mayo Clinic and the support from National Indian Health Board further strengthens the likelihood that this will be a successful endeavor. There is an overall plan of process evaluation which will focus on assessments of the programs during the grant period and provide feedback to the collaborators for continuous improvement.

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Judith S Kaur

Innovation:

The idea of combining forces and resources to bring parity to the rest of the U.S. population in cancer prevention activities among All AN is deserving and a new challenge to the existing paradigm. Other minority populations may look to this model in the future for their collective benefit.

Investigators:

The principal investigator is highly qualified to work in cancer prevention and with Native Americans. She states her nationality as Native American and she is a medical doctor who has worked with cancer patients, and Native American families. She also had lead other successful projects with cancer prevention in the last 5 years. The supporting co investigators and the key personnel from each collaborating entity are leaders in their own cancer prevention projects or in their Native American communities.

Environment:

A proposal is complete with commitment letters from each of the collaborators. The resources committed are clearly described and delineated: Expertise, laboratories, in kind support, conferences, space, committees, and other network support are well documented. Included in the appendices is, each of the collaborator's specific proposal including their program profile, goals and objective, specific aims, budget, research plan and design for this project. The methodologies for implementation or curriculum is also included.

Reviewer #2:**Major Strengths:**

Collaboration is a major strength of this project. The collaboration efforts incorporate participation of some of the major researchers in Cancer research among American Indian/Alaska Native populations and national AI/AN organizations. The collaboration also includes participation of Universities and community organizations. One of the major strengths is the PI is American Indian.

Major Weaknesses:

There are a few limitations to the study. One is the aim of involving all AI/AN Nations into the collaboration. Until there is more uniformity within the AI/AN communities for research approvals and review this will not be implemented fully. The inclusion of the Alaska Native population will pose some unique situational problems.

Significance:

Cancer is the second leading cause of mortality for American Indians and leading cause of death among Alaska Native women. The racial misclassification that frequently occurs among this population poses a problem but illustrates the need for better data surveillance and collection especially among the urban Indian population which this project hopes to tap into.

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Judith S Kaur

Approach:

This research project utilizes existing networks already in place. It will also work on strengthening collaborations within that network and establishing new ones.

Innovation:

Bringing AI/AN Tribal Nations into the collaboration at the beginning of the project and eliciting their support is an innovative practice and initiates a trusting environment for the researchers. Utilizing the existing Indian student scientific organizations to recruit researchers is unique.

Investigators:

The investigators are nationally recognized in the field of cancer research and have already established relationships with the target populations and elicited their trust. This is a definite advantage in working with the AI/AN community. The investigators being AI is a distinct benefit to working with the target population.

Environment:

The researchers are in established research environment. The research environment is well equipped to deal with the research.

Minorities in Clinical Research Study Populations:

This aspect of the project is well delineated and outlined. They have a plan in place that will address the issue of minorities into research both for researchers and subjects. They will utilize the established training of Native Researchers into Cancer Control Research in Portland, Oregon with Dr. Thomas Becker. They will also utilize the Mayo Clinic Native WEB to train nurses to provide culturally sensitive cancer education, pap smears and clinical breast exams. The trainer for this program has a proven record of working with the AI/AN community. Women are clearly a target population here but children are not mentioned.

Protection for Human Subjects:

In the main grant, there is a statement of "pending" from IRB for this project. The document for IRB approval is absent from these forms. In collaborating partner's proposals, some marked "no human subjects" due to the nature of their partnership. Since the parties are universities, each one should have a IRB approval

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Judith S Kaur

Budget

The budget is recommended as requested.

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address: <http://www.nih.gov/grants/policy/amendedapps.htm>

NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in \$25,000 modules, without budget detail for individual categories.

Further information can be obtained from the Modular Grants Web site at

<http://www.nih.gov/grants/funding/modular/modular.htm>

NIHB's role in NCI Grant
1/11/00

ADDITIONAL BUDGET JUSTIFICATION INFORMATION

PROJECT COORDINATOR AT MAYO: This person will need to be highly skilled at organizational and communication skills. The project coordinator will report to Dr. Kaur. He /she will be responsible for the daily activities of the grant including:

1. Teleconferences with participating organizations and individuals
2. Written communications about grant activities
3. Setting up and attending Steering Committee and Advisory Board meetings
4. Materials development to advertise the programs sponsored by the AI/AN Initiative on Cancer
5. Development of a travelling exhibit to educate about the grant and the programs it develops
6. Web-site updates on activities of the grant
7. Organizing regional meetings
8. Coordinating which members of the Steering Committee and Advisory Board will attend professional meetings
9. Presenting at the National Indian Health Board and the Association of American Indian Physicians meetings (including the Association of Native American Students)
10. Writing articles for newsletters, newspapers and magazines for Native people(AAIP, NIHB, Indian Country Today, SACNES, Winds of Change
11. Coordinating rotations at Mayo Comprehensive Cancer Center for students supported on the grant
12. Coordinating community research experiences for students on summer mini-grants
13. Setting up conferences and maintaining phone contacts with CIS subcontractors
14. Coordinating with the American Cancer Society for conference presentations on topics chosen by the Steering Committee
15. Coordinating efforts with Native WEB and Native C.I.R.C.L.E.
16. Written reports to NCI on grant functions
17. Assisting Drs. Dignan and Kaur with evaluation reports
18. Other activities and duties as designated by Dr. Kaur and the Steering Committee

NATIONAL INDIAN HEALTH BOARD MEMORANDUM OF AGREEMENT

The NIHB will be an active participant on this grant to

1. co-sponsor regional as well as national meetings,
2. provide updates in its newsletter,
3. actively recruit students and physicians for grant activities,
4. assist with designing the mini-grant process
5. disseminate information throughout Indian country on the workings of the grant.

To do this appropriately, we have budgeted funds of \$75,000 for the first year and \$100,000 for subsequent grant years to support conferences throughout the country as well as specific communications to all tribes informing them about the grant activities and goals. The NIHB representative will be a permanent member of the Steering

Committee. We will look at all meetings attended by Native professionals (physicians, nurses) to provide cost-effective coverage with workshops and other presentations designed to meet the goals of the grant as stated in the specific aims.

American Association of Indian Physicians: Funds are requested to provide workshops for native students and American Indian physicians at the AAIP annual meeting. The money will be needed to provide travel scholarships to students to attend the workshops and to reimburse AAIP for the FTE needed to set up the workshops, advertise and coordinate the program to meet the specific aims as outlined in the details of Specific Aims 2 and 3.

See further specifics on NIHB Budget Justification attached.

For subcontracts with University of Arizona, Oregon Health Sciences University, Fred Hutchinson, and University of Wisconsin. See complete subcontract with budget justification included.

NIHB Budget Justification:

The National Indian Health Board (NIHB) is committed to working with the American Indian/Alaska Native (AI/AN) Initiative on Cancer Project by providing direct support in order to attain the goals of the project. The NIHB involvement on this project has been categorized into three specific areas with their costs as follows:

1. Newsletter Activity, Quarterly Meeting Updates, Organizational informational releases, project updates on NIHB website.	\$25,000
2. Annual Consumer Conference Activity:	\$ 35,000
3. Link Tribes not Served by CIS	\$ 15,000
Total	\$ 75,000

Newsletter: The NIHB produces a quarterly newsletter entitled, *The Health Reporter*, with a circulation to over 5,000 individuals working or interested in AI/AN health care programs. The normal layout for *The Health Reporter* includes 16-pages of health care issues affecting AI/AN tribal health care programs. For the purposes of this grant, a special 4-page insert will be added to each newsletter to feature the activities related to the project. The NIHB contracts with a graphic artist to assist in the development and layout of the newsletter. It is anticipated that the page special feature will take 60 hours of design and layout work at \$65/hour for a total of \$2,925. An average cost of past *Health Reporter* print production is approximately \$7,250 (\$1.45 per copy), it is estimated to produce an additional 4 pages will be 20% of this cost or \$1,450. The cost for film output for each newsletter is \$1,000. Miscellaneous supplies and other costs associated with the production of each newsletter is estimated to be \$875. The cost to do each quarterly newsletter is \$6,250 and the total cost to do four newsletters for a year is \$25,000 (\$6,250 x 4).

Annual Consumer Conference: Each year the NIHB conducts an Annual Consumer Conference so that tribal officials and health care providers can share their concerns, their challenges, and their recommendations for improving health care-delivery in forums designed to provide training, technical assistance and appropriate policy discussions. The conference is conducted in close association with the local tribes represented by their Area Health Boards. For the purposes of this application, the NIHB utilize workshops at its conference to address the goals of this project which include: assisting in the development of infrastructure to support a nationwide initiative on cancer, developing collaborations with tribes and other organizations; bringing together AI/AN researchers and others involved in cancer control to meet during the conference; showcase educational programs on cancer and bring together cancer survivors and community based groups; and assist in strengthening the overall collaborations among AI/AN communities with NCI, CIS, and ACS by providing them a forum to network at each consumer conference.

The cost to host a conference of this size and scope exceeds \$150,000. At NIHB's 1997 Spokane Conference there were over 850 participants, while the 1998 Anchorage Conference exceeded over 980 participants. This year's event will be held in San Diego and attendance is anticipated to exceed 1,000 participants. It is estimated that the costs to plan and develop the conference activity for this Initiative will be approximately \$35,000. These costs include staff

time to plan and coordinate on-site activity, develop cancer agenda, confirm presenters and speakers, prepare and produce handouts, and other activities associated with conducting a national meeting.

Link Tribes not Served by CIS: Because there are tribes who are not covered by the Cancer Information Service (CIS) the NIHB staff and Area Health Board representatives will work aggressively to link those tribes to the American Indian/Alaska Native Initiative on Cancer activities. The cost to conduct this portion of the project is estimated to be \$15,000 for the first year. The first year of the project will be committed to project start-up activities, however for the ensuing years of the grant, this activity will increase marginally and it is anticipated to cost \$40,000 per year.