

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

ANNUAL REPORT

JANUARY 1986

FY 85-86

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

ANNUAL REPORT

JANUARY 1986

FIRST ANNUAL REPORT

TABLE OF CONTENTS

<u>Item</u>	<u>Page</u>
Membership	1
Acknowledgements	2
Background.....	3
Activities of the Commission	4
<u>Appendices:</u>	
A- Arizona Revised Statute 36-271	5
B- Minutes, 1985 Meetings	9
C- Request for Competitive Sealed Proposals, Fiscal Year 1985-86	26
D- Description of Proposals Submitted	42
E- Description of Proposals Approved for Funding	45
F- Contract and Workstatement, Fiscal Year 1985-86.....	50

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

MEMBERS

Ex-officio Chairman

Lloyd F. Novick, M.D.
Director
Arizona Department of Health
Services
1740 W. Adams
Phoenix, Arizona 85718

General Public Representatives

Peter Baird
Attorney at Law
First Interstate Bank Plaza
100 W. Washington
Phoenix, Arizona 85003-1899

Isabel Fathauer
1915 E. Camino Miraval
Tucson, Arizona 85718

Maxine Marshall
Associate Publisher
Scottsdale Daily Progress
Box 1150
Scottsdale, Arizona 85252

Executive Staff Assistant

Linda M. Udall, M.P.H.

Medical Community Representatives

Robert Brooks
St. Joseph's Hospital
and Medical Center
350 W. Thomas Road
Phoenix, Arizona 85003

Ralph Jackson, M.D.
Box 12650
Tucson, Arizona 85732

Louis Newton, M.D.
1300 N. 12th Street
Suite #612
Phoenix, Arizona 85006

Scientific Research Community
Representatives

Mary Hendrix, Ph.D.
Department of Anatomy
University of Arizona
Tucson, Arizona 85724

Susan Wyckoff, Ph.D.
Physics Department
Arizona State University
Tempe, Arizona 85287

Acknowledgments:

Rhonda Hartman's support of the Arizona Disease Control Research Commission in its initial stages was indispensable. She has dedicated countless hours of creative energy to insuring that the directives of the Commission were proficiently accomplished. In addition, the rapid and efficient support of the Commission's business by the administrative staff in the Office of the Director, State Department of Health Services, has been invaluable.

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

Background:

The Arizona Disease Control Research Commission (ARS-271 et. seq.) was established by the Arizona Legislature and signed into law by Governor Bruce Babbitt in 1984 (Appendix A). The Commission was created to advance medical research. It is unique throughout the United States in its mission to fund investigators who are to focus on disease problems important to state residents.

The Commission has the authority to utilize monies from the Disease Control Research fund to contract for projects and services that advance research into the causes, epidemiology and/or diagnoses of diseases. The Commission can also contract for research in the formulation of cures and medically accepted treatment or prevention of disease. Prevention can include new drug discovery and development.

The Commission has ten members: three members representing the medical community, three members representing the scientific research community, three members representing the general public and the Director of the Arizona Department of Health Services who serves as ex-officio Chair of the Commission.

In fiscal year 1985-86, the fund will receive a total of \$900,000. In succeeding years, the fund will grow to a minimum level of \$2.97 million. The Commission can also accept gifts, contributions or other monies to enhance the amount collected from delinquent taxes to augment the fund.

The statute requires that the Commission establish a subcommittee to review and evaluate proposals and recommend funding allocation to the entire Commission. The Commission is also charged with establishing a mechanism to review contract awards to ensure accountability.

ACTIVITIES OF THE ARIZONA DISEASE CONTROL RESEARCH COMMISSION

There were five meetings of the Commission in 1985 held on June 12, July 31, August 31, November 4, and December 12 (Appendix B).

Guided by the Arizona Department of Health Status Report developed within the Arizona Department of Health Services, Commission members established four areas of research within which they would accept proposals. These four priority areas were; malignant neoplasms, pulmonary diseases, infectious diseases, and "other" (which included proposals that did not fall into any other category and were particularly relevant to the health problems in Arizona).

The Commission decided that the projects should be submitted within certain parameters relative to the scope of the research and the proposed budget. They delineated three areas; small, intermediate, and large. Small projects were restricted to a budget under \$15,000; intermediate projects to under \$100,000, and large projects had no funding limit. Proposals submitted in the priority area of "other" were restricted to either the small or intermediate project categories.

The Commission offered letters of intent to the research community, announcing that funds were available for research and a request for proposals was forthcoming. The availability of funds for disease control research was also publicized in the media. The "Request for Proposals" (RFP) were mailed to persons indicating an interest, with a return deadline of October 18, 1985 (Appendix C). One hundred and fifty-six proposals were received (Appendix D).

The Commission divided into three subcommittees and reviewed these proposals for relevance to the priority areas and on the scientific quality of the research. It was decided that only the intermediate and large projects would be subject to a peer review, pending recommendation by the subcommittees. Each subcommittee compiled ratings of the proposals and made recommendations to the full Commission about whether a proposal should be sent to peer reviewers or, for small proposals, whether a proposal warranted further review by the entire Commission.

Decisions to fund small projects were based on subcommittee recommendations and discussion by the Commission as a whole. The funding of intermediate and large projects was contingent on the comments of peer reviewers as well as the Commission's evaluation of each top proposal. The Commission gave careful consideration to many facets of the proposals; relevance to health problems in Arizona, merit of the study design, technical feasibility, specificity of projected goals, etc.

Twenty four of the 156 proposals submitted were approved for funding (Appendix E). The majority of the funds will be supporting cancer research in the state. Other projects receiving awards for conditions important to Arizona include research on AIDS, Alzheimers disease, Valley Fever, rattlesnake bites, stroke, and diabetes. The conditions of these awards were discussed with each recipient. Expenditure reports are required to apprise the Commission of progress towards the research goals. A final summary of the progress and accomplishments of the research is required at the end of the fiscal year (Appendix F).

APPENDIX A

Arizona Revised Statute 36-271:

Arizona Disease Control Research Commission

Termination under Sunset Law

The disease control research commission shall terminate on July 1, 1994, unless continued. See §§ 41-2368 and 41-2377.

Article 4 relating to the disease control research commission is repealed on January 1, 1995. See § 41-2376.

Laws 1984, Ch. 353, § 1 provides: means of funding research into the causes, treatments and cures of disease."
 "The purpose of this act is to improve the health of the people of this state by providing a

§ 36-271. Definitions

In this article, unless the context otherwise requires:

1. "Commission" means the Arizona disease control research commission.
 2. "Disease" means a condition or disorder that causes the human body to deviate from its normal or healthy state and which condition or disorder has no known general cure or adequate medically accepted treatment.
 3. "Medically accepted treatment" means a methodology or protocol recognized by the American medical association, the American college of surgeons or the national cancer institute or taught by an approved school of medicine as defined in § 32-1401 as a treatment that results in the restoration of the human body to a normal or healthy state.
- Added by Laws 1984, Ch. 353, § 2.

1981 Reviser's Note: transposed pursuant to authority of section 41-1304.02.
 In paragraph 3 "or" following "association" and the comma following "surgeons" were

§ 36-272. Disease control research commission; members; terms; appointment; compensation; chairman; meetings

A. The disease control research commission is established, consisting of the following members appointed by the governor pursuant to § 38-211:

1. Three members representing the medical community who are experienced in disease related research, no more than one of whom may be employed by or otherwise associated with any state agency, state university or political subdivision of this state.
2. Three members representing the scientific research community, no more than two of whom may be employed by or otherwise associated with any state agency, state university or political subdivision of this state.
3. Three members representing the general public.

B. The terms of members are three years beginning on the third Monday in January.

C. Members are eligible to receive compensation pursuant to § 38-611.

D. The director of the department of health services is an ex officio member of the commission and shall serve as chairman without compensation.

E. The commission shall meet at least quarterly at the call of the chairman.

Added by Laws 1984, Ch. 353, § 2.

Laws 1984, Ch. 353, § 5 provides:

"Sec. 5. Initial terms of members

"Notwithstanding § 36-272, Arizona Revised Statutes, as added by section 2 of this act, the initial terms of members of the disease control research commission are as follows:

"1. One member each from the medical community, the scientific research community and the general public, each of whom shall serve for a one year term.

"2. One member each from the medical community, the scientific research community and the general public, each of whom shall serve for a two year term.

"3. One member each from the medical community, the scientific research community and the general public, each of whom shall serve for a three year term."

Library References

Health and Environment §3.

C.J.S. Health and Environment §§ 9, 10.

§ 36-273. Powers and duties

A. The commission may:

1. Utilize monies in the disease control research fund established pursuant to § 36-274 to contract with individuals, organizations, corporations and institutions, public or private, in this state for any projects or services that, in the commission's determination, may advance research into the causes, epidemiology and diagnosis, the formulation of cures, the medically accepted treatment or prevention of diseases including new drug discovery and development. No public monies in the disease control research fund shall be used for capital construction projects.

2. Accept or receive monies from any source including restricted or unrestricted gifts and contributions from individuals, foundations, corporations and other organizations and institutions.

3. Obtain expert services to assist in the evaluation of requests and proposals by the subcommittees of the commission. The commission may request cooperation from any state agency for the purposes of this article.

B. The commission shall:

1. Establish a subcommittee to review and evaluate proposals or requests for projects or services and recommend to the commission the allocation of available monies.

2. Establish a mechanism to review the contracts awarded to ensure that the monies are used in accordance with the proposals approved by the commission.

3. Prepare and submit a report on or before January 15 of each year to the governor, the president of the senate and the speaker of the house of representatives. The report shall describe the activities of the commission, the projects or services proposed to the commission, the projects or services for which the commission has awarded a contract and the amount of monies necessary for each proposal, the cost of each proposal for which a contract was awarded, the names and addresses of the recipients of each contract and the purpose for which each contract was made.

Added by Laws 1984, Ch. 353, § 2.

Library References

Health and Environment ⇄6.

C.J.S. Health and Environment § 13.

§ 36-274. Disease control research fund

A. The state treasurer shall maintain a fund known as the disease control research fund to consist of monies received pursuant to subsection C of this section, monies appropriated by the legislature and any gifts, contributions or other monies received by the commission from any source.

B. The commission may expend monies in the disease control research fund for projects or services pursuant to § 36-273 and for expenses incurred by the commission in carrying out the purposes of this article.

C. Notwithstanding any other provision of law to the contrary, each fiscal year, from the amount of monies collected from penalties or interest on delinquent taxes pursuant to titles 42 and 43¹ which would have been deposited in the state general fund, the following amounts shall be deposited by the state treasurer in the disease control research fund established pursuant to this section:

1. From amounts collected in fiscal year 1985-1986, nine hundred thousand dollars;

2. From amounts collected in fiscal year 1986-1987, two million two hundred seventy thousand dollars;

3. From amounts collected in fiscal year 1987-1988, two million five hundred seventy thousand dollars;

§ 36-274

PUBLIC HEALTH AND SAFETY

J. From amounts collected in fiscal year 1988-1989 and each year thereafter, two million nine hundred seventy thousand dollars.

The monies collected from penalties or interest on delinquent taxes pursuant to this subsection shall be deposited up to the total dollar amounts prescribed for such fiscal year, subject to availability, on a monthly basis.

D. Monies in the disease control research fund are exempt from § 35-190 relating to lapsing of appropriations.

Added by Laws 1984, Ch. 353, § 2.

¹ Sections 42-101 et seq. and 43-101 et seq.

Cross References

Use of monies in fund, see § 32-273.

C.J.S. States § 223.

Library References

States ⇐127.

APPENDIX B

Minutes

1985 Meetings

MINUTES

ARIZONA DISEASE CONTROL RESEARCH COMMISSION JUNE 12, 1985

Present: Dr. Lloyd Novick, Chairman
Peter Baird
Robert Brooks
Dr. Mary Hendrix
Maxine Marshall
Dr. Louis Newton
Susan Wyckoff

Absent: Isabel Fathauer
Dr. Ralph Jackson

Staff: Gloria Heller
Rhonda Hartman

Dr. Novick called the meeting to order and described the excellent opportunity presented to Arizona by the creation of this Commission for health research. The Commission has been funded to contract with institutions and individuals for health research projects. There will be \$900,000 available beginning July 1, 1985.

Several organizational and planning topics were discussed, including:

1. Purpose of the Commission. There was discussion about community understanding of the Commission and its purpose. The members discussed scope of the Commission and whether guidelines were necessary to establish scope and target specific issue areas such as cancer, Alzheimers disease, valley fever, etc.
2. Research Awards. Members discussed what type of awards could be made (small investigative grants or large block grants) and who could receive grants (universities, individuals, small groups). Commission members discussed whether limitations can or should be placed on who can apply, the amount of the application and whether the Commission can check on the past performance of grant applicants. Questions were also raised about whether treatment could be funded. Treatment does not seem to meet the intent of funding research projects.
3. Review Procedures. There was discussion about the different types of review procedures that could be used to evaluate proposals. The statute requires the Commission to establish a subcommittee to review proposals and make recommendations about funding. The actual review procedures are not specified. Discussion centered around creating an appropriate quality review mechanism, which could include some type of peer review. Mr. Brooks asked whether an accepted application had to be funded totally or whether it could be funded partially. The proposal review committee will need to investigate this issue.

Timeframes for developing the requests for proposals and review guidelines were discussed. It may be necessary to create an initial work plan in a future meeting.

4. Commission Staff. The Commission has the authority to hire staff to carry out its functions. Staffing requirements were discussed and need to be resolved at a future meeting.

Mr. Baird moved that notices should be sent to individuals, organizations, health care facilities, journals, papers, etc. stating the broad charge of the Commission and inviting letters of intent about projects that may require funding. MSC.

The letter of intent should solicit the title of the project, a synopsis of the project, and funding. Budgetary stipulations and the amount allowed for indirect costs and equipment need to be resolved.

Gloria Heller discussed state procedures for contracts and RFP's and said they must not be vague, but must take statutory language, and get structure and definition before doing RFP's.

Rhonda Hartman explained that, since the Commission was not exempted, it will be following the Arizona Procurement Code and Department of Administration Rules and Regulations. There have been many changes to the code in the last two years. Rhonda Hartman will be checking details with the Attorney General's Office.

The next scheduled meeting will last approximately two hours. Some other people doing research in Arizona may be invited to speak and share their ideas on the monitoring of how funds are spent by contractors, etc. Dr. Salmon, Dr. Petit, Dr. Lou Kettal and John Murphy were suggested as possible speakers.

The Health Department will send out the notice to the public and will forward Commission members copies of the letters and materials that are mailed out.

Charlene Wilkins
Recording Secretary

MSC = Motion Seconded Carried

DISEASE CONTROL RESEARCH COMMISSION MEETING MINUTES
July 31, 1985

Members Attending:

Dr. Lloyd Novick, Chairman	Dr. Louis Newton
Maxine Marshall	Isabelle Fathauer
Dr. Mary Hendrix	Peter Baird
Dr. Robert Brooks	

Guest Speakers:

Dr. Syd Salmon	Dr. Lou Kettel
Dr. Pettit	Dr. John Murphy

Members Absent:

Susan Wyckoff	Dr. Jackson
---------------	-------------

The meeting was opened at 11:15 A.M. by Dr. Novick.

Dr. Novick called the meeting to order and briefly described the agenda items.

Health Status Report: Dr. Novick explained that the major problems from a population point of view may be different from individual clinician problems. Infant mortality is the greatest problem in Arizona. While Arizona compares favorably with the nation, the national rate is less than desired. Arizona's rate is 9.7 per 100,000. The goal is to reduce that rate to 7 per 100,000. The rate among Blacks is twice as high as both White and Hispanic in Arizona and the nation. Teenage pregnancies, unwed status, other medical problems, and nutrition all contribute to difference among ethnic populations.

There are additional problems. A number of letters were received regarding heart disease which is the leading cause of death in Arizona. The Arizona rate is significantly less than the national rate. It may be due to a selective migration factor. The most striking factor is the 25% reduction in deaths over the last 15 years which is not related to improved treatment. It may be due to a change in life style, i.e., smoking cessation, diet, hypertension control and exercise.

Cancer is the second leading cause of death in Arizona. There were many letters of interest in this area. The Health status summary points out differences in female mortality from cancer. Lung cancer is replacing breast cancer as a leading cause of death for women.

Chronic obstructive pulmonary disease is much higher in Arizona than the national rate. The female rate of death doubled since 1970, and may be due to smoking. Cerebrovascular disease has declined about 40% over the last 15 years due to better control of hypertension.

Only one letter of inquiry received about the disease of alcoholism. This prevalent disorder associated with personal and other disruptions.

Suicide is the sixth leading cause of death in Arizona. Arizona has one of the highest rates of any state. ADHS is interested in both adolescent and elderly suicides.

Accidents in Arizona exceed the national mortality rate. Drowning is the leading cause of death for children 1-4 years of age. Motor vehicle accidents is the next leading cause of death. ADHS contacted other states for drowning data and the information compared

states by proximity to bodies of water and by climatic region. Arizona's major difference from other states is in the 1-4 year old category. Arizona and Florida have the highest rates of drowning deaths. Thirty children, or 3/4 of drownings, happened in Maricopa County.

It may be interesting to discuss with guest speakers about organizing research funding around the major causes of death. This could be one strategy, but there is also an interest in morbidity among the living.

Dr. Novick expressed some particular biases toward looking at health of populations as well as individuals.

Mr. Baird expressed concern that there may be some difficulty in funding non-disease causes of death such as accidents. He does not believe the legislation is written in a way to give the Commission such a free hand.

There was discussion about a statewide tumor registry. Dr. Novick said that a request for sufficient funding for a statewide tumor registry will return to the Legislature this year. This may have research application. Defining accidents as a disease requires thought. People who incur accidents have a change in pathology and physiology which relates to the statutory definition of a disease. An experimental model may be used for drowning and accidents, while medical approaches after death are related to treatment.

There was discussion about accidents, suicide drowning and alcoholism as areas that could be considered diseases, and thus eligible for funding.

Mr. Baird read the statutory definition of disease. A disease is a condition or disorder that causes the body to deviate from its normal general state and for which there is no known natural cure. Drowning could meet this definition.

Discussion of Research Summaries Received

Commission members were sent the first group of letters which came in from U of A. There was a brief summary of area and costs. The cost of the first letters received totaled approximately the entire budget for the first year. A number of letters were received since these were sent out. A total of 113 letters of inquiry were received as of July 30, 1985. Since there is a mid-August cut-off date, additional letters are expected.

Ms. Marshall asked about the advertising which included announcements to the three major universities, to all hospitals, articles in the Republic, the Tucson papers, and in the Scottsdale Progress; announcements in the Pima County and Maricopa County medical society journals and a T.V. spot on Channel 5. Commission members thought it was necessary to increase advertising about the Commission.

There was a discussion about what the focus of the Commission should be for funding purposes. The general consensus seemed to be that the commission should focus funding on medical research for leading causes of death in Arizona. The burden of proof should be on the applicant to explain how their project meets the requirements of the statute. The Commission is authorized to obtain consultation from experts about projects.

Commission members asked the guest speakers to attend the meeting to help in grappling with questions facing the Commission. What research interest should receive funding?

What is the historical genesis of the Commission? What sort of mechanism should be used to judge applicants if the project is not in anyone's area of expertise? Should the Commission focus on certain areas of interest such as the heart disease, cancer, etc?

Dr. Novick introduced the guest speakers. Dr. Salmon began the discussion.

Dr. Salmon:

The final legislation for the Disease Control Research Commission is very different from how it started. It evolved from cancer research to heart disease and pulmonary disease, and finally to general research. However, it is very worthwhile. Questions about basic research and how basic are very important. The Commission needs experts, and can decide the best model for review. Limits need to be decided about clinical outreach, epidemiology and prevention. No one knows in advance what is relevant. Something not thought essential at first may turn out to be essential. The Commission needs some way of identifying a project's relevance or it is hard for an investigator to make a decision about seeking funds. The applicant should make a statement about the project's relevant to disease research and what disease or diseases are to be studied. A lay statement should be required so lay members of the Commission can understand the project. The Commission may want to look at (1) individual research projects and programs; i.e., one investigator, own lab, small in size. These are not large-scale, but sometimes are very important; and (2) program projects, i.e., a series of investigators with a common goal. Many projects need to be funded for more than one year. Generally, the investigator does seed work and knows if the project is feasible. In these projects, the data base needs review. The Commission may receive a tremendous number of seed projects. It may not be wise to put a huge amount into the projects. Money should go where the feasibility is not in question, like heart disease, diabetes, cancer, etc.

In addition to some individual projects of longer duration than the year, there might be large commitments for a one year time period. If there is no way to measure, show, or demonstrate achievement of certain objectives, it should be put aside.

There are other issues. Equipment requests are difficult to judge because the research is unknown. On the other hand, lab research is combination of equipment and personnel. More equipment might be required early on. Equipment needs must be adjusted or related to research throughout.

If research involves clinical human subjects or animal subjects, ensure that appropriate institutions comply with federal guidelines.

Dr. Kettel was introduced.

Mr. Baird was interested in knowing whether proposals to funding entities are on a standard form of some sort, and if so, what does the form look like? Could the Commission receive a copy? What are some of the criteria to compare things? Does the standard format include a definition of disease. Is each applicant asked a minimum number of questions so lay people can have a better comparison for making judgements?

Dr. Salmon responded that there are standard forms and informational brochures to mail to potential applicants. He would be happy to provide a National Institute of Health form which has most of the information necessary. An additional check list may be necessary to categorize projects. NIH looks at the title and assigns it to a special review group before it ever gets to a Commission like this. A standard form should be used. A staff member ensures that a lay statement and check list are provided. Peer review is extremely important. The NIH model has a large number of standing committees very

familiar with specific disease areas, and has interdisciplinary committees such as pathology. It may be too expensive to have standing committees for this Commission, since funds are limited. National Science Foundation has a mail review to out of state places to avoid conflict of interest. A strict time frame is necessary for receiving response.

When applications are reviewed, they fall into two general categories-disapproved and approvable. Unapproved applications are refused for funding, the others are ranked by priority score. For scientific reasons this can be at subcommittee level. Over all, funding really depends on the Commission, not a subcommittee. The Commission must decide what model it wants.

Dr. Kettel emphasized the relatively small amount of money available. It could soon be used up on consultants. How can the Commission be cost efficient in the beginning? (1)It can have some idea how best to spend its funds; and (2)let people know the grant rules. It is frustrating to get 100 letters in and plan to reject 90% of them. The grant rules should be delineated quickly.

Depending on preciseness of grant rules, other limits may be placed on funding. The limit is small, the researcher has to decide whether to apply for partial funding of the project. The Commission must decide if it wants to fund only part of a project. Developing grant rules is very important. Equipment is a problem because costs are increasing. Many institutions are limited by absence of equipment. It will be tempting to use this fund to build up equipment. Be precise in how far the Commission will go in funding equipment and let researchers know ahead of time. There is also a question of construction and remodeling.

Mr. Baird said that capital construction projects are not allowed.

Dr. Kettel:

Dr. Kettel asked about remodeling to fit equipment in. Mr. Baird felt that remodeling for installation of equipment could be approved. Dr. Kettel advised that applicants should be asked if they plan to apply for equipment and, if so, would the equipment require remodeling? Grant application should also include an explanation of what resources are needed secondarily, i.e., computer resources. It is difficult to do appropriate evaluation without data analysis. A red flag area is animal resources. Are animals available in adequate amounts? Site visits might be necessary and may need to include this in the Commission budget. It may be helpful to do a mailing asking researchers how they think the funds can best be used; i.e., major institutions. If capital equipment replacement turned out important, set aside approximately \$200,000 per year. With limited dollars the most likely solution is to limit categories you will fund for research. Investigators probably would not resent it if the Commission focused on cancer this year, heart disease next year, etc. Some future issues include adding a caveat limiting projects to the State of Arizona and why this project is of interest to Arizona? Money could be divided for seed programs, equipment and so forth. Applicants must be asked where else they have applied or received grants from.

Dr. Pettit was introduced.

Dr. Pettit:

The original bill was based on creating cigarette tax and using the funds for a specific attack on the cancer problem. He spoke about organic chemistry and the isolation of morphine, which was an important breakthrough linked to all drugs used today for pain relief. Chemical modification appears to be the first breakthrough. The Commission

should consider focusing brain power and funds on two main things: (1) Developing drugs for cancer treatment, developing the drugs, supporting the clinical facilities and resources necessary to deliver the drugs. It is possible to have a terrific impact if those two things are emphasized. The feature that is always missing is funding to actually provide new drugs. Arizona has an opportunity to be in the forefront of solving some very severe problems. The committee should make decisions based on what will most sharply focus energies on curing patients and on providing a role model for other states.

Mr. Baird asked what kind of methodologies, forms, applications, criteria and protocols are necessary to better evaluate requests?

Dr. Pettit responded that the evolution of the National Institute of Health (NCI) application form has improved amounts of information received. The Commission should ask for a summary of research, the importance of the research, where the research is leading, a precise budgetary analysis, specific names of research, methodology of accomplishing what is proposed, credentials of researchers, and credentials of those assisting in labs. National Cancer Research Center is not as rigorous, but they require more detail about the results the researcher is after.

Dr. Hendrix pointed out that the NIH forms are quite thick and limitations should be placed on that. Commission members agreed.

Dr. Hendrix questioned whether the Commission would be in any jeopardy with limiting research to cancer drugs and delivery.

Mr. Baird responded that he was unsure but his first reaction is for the first year or two to focus on one cause. The Commission should review the statistics on tables in the Health Status Report to decide what limits should be set. It is the Commission's discretion to decide what to do.

While Dr. Pettit said his original feeling was a hope that the entire focus would be on cancer, he would spur the Commission to proceed as they wished. When the first proposal was made to State Legislature, he hoped that at least 50% would go to UofA Cancer Center and 25% to 30% to cancer research at ASU. His rationale is the cost of cancer deaths in Arizona. He also pointed out when NIH began cancer research in 1955 people believed that conducting research on cancer problem was professional suicide. Fortunately, NIH progressed and within a year found a cure for carcinoma in pregnant women. Now, 50,000 people per year are being cured who could not be cured by surgery and radiation. Discovery of new drugs is very important. This state has a great opportunity now to do this. Cancer can be conquered if funds are spent judiciously. It may require site visits and evaluation of labs. NIH does this routinely.

Dr. Murphy was introduced.

Dr. Murphy:

Dr. Murphy asked about the budget. Dr. Novick explained that there is \$900,000 the first year and this increases to \$2.9 million annually in succeeding years. Dr. Novick asked Dr. Murphy to explain how the Commission can spend money effectively through use of the application process, setting priorities and objectives and reviewing applications.

A second question involves funding projects similar to the Flinn Foundation projects. Should the Commission be thinking of that?

Mr. Murphy addressed these points from the experience of the Flinn Foundation. One problem they encountered is receiving many proposals which were quite technical, while the board is composed of lay people or physicians without expertise in such fields.

The second problem is trying to understand the dimension of proposal involved. Some applicants, while capable, were turned down by other capable review groups. They evaluated whether they be supporting projects that had failed peer review and were not competitive. The Flinn Foundation decided they would take advantage of established peer review processes where possible. Their foundation took proactive steps to define research fields in which they would accept proposals. In turn, they selected a review panel. The names are kept confidential. The review panel reviews applications and then assembles at some site to rank them in order.

Arizona affiliate of the American Heart Review Association, which has good efficient existing peer review processes include the Arizona affiliate of the American Heart Review Association and the University Medical College where peer review is carried out by the basic science research committee. That has worked well for Flinn Foundation which pays a fee for such services.

By and large, local researchers have not fared well nationally against peers from some other states. They may be capable, but the track record is not well established in Arizona for medical research. A decision needs to be made regarding how many grants can be assured within the state, i.e. one large or several smaller ones. Does the Commission want to solve large problems like cancer, or foster and encourage research through several smaller grants.

Evaluatory procedures are necessary to determine if anything is accomplished. If the evaluators know that is to be accomplished, can they evaluate more effectively? An evaluation can include receipt of reports on time, by contributions made to cancer research in Arizona, or by declining rate in cancer deaths. It is important to clearly delineate what is to be accomplished. One other accomplishment may be to enriching or strengthening research capabilities in the state in certain fields.

Dr. Hendrix asked if the review committees are paid or provided an honorarium.

Dr. Murphy responded that they are paid \$100-\$200 for their assistance.

The entire review process takes 6-8 weeks. It is not always necessary to pay for reviews if an existing process is used. The Arizona Heart Association has a state peer review as well as joint review with New Mexico and Arizona.

Dr. Novick stated that in terms of funding medical research, the two largest sources will be the Flinn Foundation and this Commission. What should the relationship be between the two groups. The initial emphasis of the Flinn Foundation is on heart disease. Should that affect the work of the Commission in funding certain areas like heart disease?

Dr. Murphy believes the two organizations should complement each other.

Mr. Baird asked how the review panels are kept confidential and how reviewers are located.

Mr. Murphy confers with others who are involved in various health fields. He has a universe of names available both in and out of the State. The reviewers usually do not

know each other until they convene to rate the projects. He always looks for a mixture of people, i.e., those who know blood flow as well as pump. The board makes the final decision based on the review and recommendations of the review panel.

Dr. Salmon believes it is necessary for outside peer review. An initial screen is necessary to determine what should go for peer review and what is non-responsive.

Dr. Kettel stated that it may be useful to convene a panel to give counsel in constructing RFP. Then, use two or three of that group on the actual RFP review panel.

Dr. Murphy stated they have currently \$400,000 in research grants in the state from the Heart Association. Some of that is a fellowship program.

Mr. Baird pointed out that if people from the Universities cannot be used as peer reviewers, it may be difficult to find expert consultants in Arizona.

Dr. Salmon stated that other states, like California, or national panels may be a good answer.

Mr. Murphy stated that one possible resource is the Research Corporation in Arizona. Dr. Schaffer is administering it in Tucson. They are closely identified with the universities and what is going on in research.

Dr. Salmon pointed out that acquiring source of names independent from those being reviewed is important and recommended that out of state people be used almost entirely. The National Institute of Health Analysts publishes a list of names and diseases covered. They weed out those who do not do a good job. Reports are anonymous as far as who made what decision, but names of reviewers are appended to reports now.

Dr. Novick thanked the guests and said the Commission may need more consultation in the future on some of these mechanisms.

Dr. Novick discussed the need of a staff person and secretary for Commission. Funding permits that. If the Commission approves, recruitment can begin. He suggested forming a screening committee to interview candidates with experience in scientific research and in administering contracts. The salary range is a state salary range for a Grade 21 position. It is the same salary range as other government councils.

Dr. Newton moved authorizing Dr. Novick to proceed as he has outlined to fill the positions of Executive Staff Assistant and Administrative Secretary. MSC

A discussion took place about the time frame for the contract process and development of the RFP. In order to sign contracts by the end of this year, it is necessary to develop an RFP by Sept. 1 - Sept. 15. The RFP must contain a description of to what people should respond to, i.e., certain disease categories, equipment, basic science, research, etc. and if there is a dollar limitation. This issue should be the subject for the next meeting.

Mr. Baird suggested that a rational way to restrict the RFP is the leading causes of death in Arizona. A preliminary discussion ensued about how to determine which disease categories should be funded, if a time commitment beyond one year is necessary for certain projects, and if funding per project should be limited.

The suggested budget was discussed. Dr. Newton moved to approve the budget as distributed. MSC

Someone must be authorized to approve expenditures for the Commission.

Dr. Newton moved to authorize Dr. Novick. MSC

Dr. Hendrix provided material about how grants are handled by Research Corporation.

Dr. Novick asked about any other business. There was none. The major items for the next meeting are structuring the RFP and deciding the funding levels.

The meeting adjourned at 2:40

MSC = Moved, Seconded, Carried

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

MINUTES

August 21, 1985

MEMBERS PRESENT:

Maxine Marshall
Susan Wyckoff
Isabel Fathauer
Dr. Mary Hendrix
Dr. Robert Brooks
Dr. Lloyd Novick

MEMBERS ABSENT:

Dr. Ralph Jackson
Dr. Louis Newton
Peter Baird

Dr. Novick called the meeting to order on August 21, 1985 at 12:15 PM. Dr. Novick asked for approval of the July 31, 1985 minutes. The minutes were approved.

Dr. Novick stated that the Commission received approximately 200 responses to the letter of intent, and briefly stated the types of projects that were proposed.

The next item on the agenda was to identify the Disease Categories for the Request for Proposal (RFP). Dr. Hendrix suggested that the following categories be discussed: Malignant Neoplasms, Cerebrovascular and Neurological Diseases, Pulmonary Diseases, including Chronic Obstructive Pulmonary Disease, Diabetes, Infant and Childhood Diseases, and Alcoholism. These priorities were suggested because they represent the leading causes of death for Arizonans, according to the Health Status Report developed by the Department of Health Services. Discussion ensued about the number and types of priority categories that should be included in the RFP, and which proposed priority areas have access to other major funding sources. After a great deal of discussion, the Commission identified the following areas for Commission funding:

- A. Malignant Neoplasms (Cancer)
- B. Pulmonary Diseases, including Chronic Obstructive Pulmonary Disease
- C. Infectious Diseases
- D. Other

The Other category will need specific explanation. This category should be restricted to small grants that do not fall into any of the other categories and have particular relevance to the health problems of Arizonans. This category should be used to encourage creative research done by one to three principal investigators.

In addition to priority categories, the type of project was discussed. This includes small projects, intermediate projects and large/multidisciplinary projects. The differences among these types of projects focuses on the number of principal investigators involved in the project, and the scope of the project, ie. the need to include investigators from various scientific backgrounds. It was determined that there would be three project categories: small, intermediate and large. The Other category will be restricted to small or intermediate program projects. The small project category will be limited to projects costing less than \$15,000. This amount includes indirect costs. The total amount to be funded in the project area is \$100,000 for FY 85-86. The other areas will not have a total funding limit.

The fourth item on the agenda was the evaluation and review process for the Proposals. Dr. Hendrix gave an overview of a suggested review process. The process included use of an advisory group of external reviewers to evaluate the proposals for technical competency. The Commission would determine how many people are necessary to evaluate each proposal. Discussion also focused on the need to get institutional approval for any research involving humans or animals before the Commission would approve that proposal for funding.

Dr. Brooks stated that the Commission must be sure that potential offerors are fiscally sound and are able to do the research they propose to do. One of the evaluation criteria will include financial stability and fiscal accountability. In addition, the Commission will require monthly expenditure reports, and has the capability to approve budgets before any expenditures are made for specific projects.

Dr. Novick pointed out that the statute requires the Commission to create a program review subcommittee. One method for the review process is to have this subcommittee make a preliminary determination about the application's responsiveness to the RFP. The proposals that passed this review would be sent to a consultant reviewer. The reviewer would rate the application, and send the rating back to the subcommittee. The subcommittee would compile the ratings and make recommendations for funding to the full Commission. The entire Commission would make the final funding decision. Discussion ensued about the number of reviewers necessary to adequately review a proposal, the expense of such a review process, and whether it was necessary for the entire Commission to be involved in making a preliminary decision about whether to send an application to an outside peer reviewer. If the entire Commission wants to be involved in the preliminary review, it may be necessary to split the Commission into three subcommittees. Each subcommittee would review one-third of the applications, and make recommendations to the full Commission about whether the proposal should be sent to an outside peer reviewer. A staff person could do a one-half page summary of the applications to speed up the process for the Commission members.

Since the Commission will not make awards until January 1, 1986, the funding will be for a six month period. The entire project amount would double once it was annualized. Since Commission funding doubles in FY 86-87, there should not be a problem in continuing support for projects that the Commission approves for funding. Contracts cannot be awarded across state fiscal years which run from July 1 to June 30 of the following year. However, projects can be approved for funding, and the Commission could contract with them if they met subsequent RFP and contract requirements and if funding was available. The RFP should ask applicants to provide both a six month and eighteen month budget so that Commission members can determine the cost of the project in succeeding years.

The Commission discussed how the RFP should be advertised. Ms. Marshall suggested that a press release be done in addition to legal requirements, ie. publishing legal notices and sending RFP's to all people already on the mailing list as a result of responding to the letter of intent.

The meeting was adjourned at 2:15PM.

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

MINUTES

NOVEMBER 4, 1985

MEMBERS PRESENT:

Peter Baird
Maxine Marshall
Isabel Fathauer
Susan Wyckoff
Robert Brooks
Mary Hendrix
Lloyd Novick

MEMBERS ABSENT:

Louis Newton

The only item on the agenda was discussion about the ranking of the proposals that were received, and how the review process would proceed.

One hundred and fifty six (156) proposals were received by the Commission - 91 in the intermediate project category, 63 in the small project category, and 2 in the large project category. Eighty-one projects were in the Other category, 38 in the cancer category, 18 in the pulmonary category, and 19 in the infectious disease category. The proposals in each of the categories were ranked from 1 (excellent) to 5 (poor) and placed in numerical order.

The Commission members discussed the types of proposals received. It was decided that those projects with numerical scores less than three would be considered for further review and funding. In the intermediate project category, the projects would be sent to two peer reviewers for a scientific evaluation. In the large project category, the proposals would be sent to three peer reviewers for evaluation. In the small category, the Commission members would review and discuss the top projects at their next meeting and determine who would receive funding. Each Commission member wanted copies of all the proposals with numerical values less than 3.0 for their further review before the meeting to determine funding.

Some discussion ensued about the two large projects (Pettit & Salmon) and the need for more specific information about the research areas.

A meeting will be scheduled in December to make final funding awards.

MINUTES
ARIZONA DISEASE CONTROL RESEARCH COMMISSION
2005 N. Central Avenue, Conference Room, 4th Floor

DECEMBER 12, 1985

Members Present: Dr. Lloyd Novick, Chairman
 Peter Baird
 Dr. Robert Brooks
 Isabel Fathauer
 Dr. Mary Hendrix
 Maxine Marshall
 Dr. Louis Newton
 Susan Wyckoff

Members Absent: Dr. Ralph Jackson

Staff Present: Linda Udall
 Rhonda Hartman
 Christine Giesselman

The meeting was called to order by Dr. Novick at 9:15 a.m.

Dr. Novick thanked Rhonda Hartman and Christine Giesselman for their help. He then introduced Linda Udall, the new Executive Assistant to the Commission

Dr. Novick reminded the Commission that the purpose of the meeting was to decide which of the top forty-seven proposals would be funded. He suggested several alternative methods for the selection process.

Discussion ensued and it was decided that the intermediate proposals would be selected first, followed by the small projects. Large projects were discussed last.

Proposals in the intermediate category were evaluated in descending order; those with an average peer review score of 1.0 or 1.5 were voted on first followed by scores of 2.0, 2.5, etc. Each proposal was briefly described by Ms. Udall. Commission members had copies of peer review comments available for perusal. Members voted yes, no, or maybe when Dr. Novick called for each decision. Votes of members affiliated with an institution who's proposal was under consideration were weighted for bias.

After all intermediate proposals had been considered those remaining undecided ("strong maybes") were revoted as "in" or "out".

Following a break for lunch, the small proposals were considered in descending order of Commission members' review scores.

Discussion of the two large projects followed. Basing their decision on the peer review comments and their own evaluations of the proposals, the Commission decided to award funding to both Dr. Pettit and Dr. Salmon. Figures of \$315,000 and \$85,000 were approved for the Arizona Cancer Center and the Cancer Research Institute, respectively,

with certain stipulations: The Commission requested that both investigators revise their budget according to the limits of the award and that the projects themselves be revised so as to more clearly and precisely define the parameters of the research. They were specifically interested in knowing; exactly what each member of the team for which support was requested would be doing, what the procedure and methodology would be for each component, and what measureable outcomes were expected.

Discussion during the day included a consensus from the Commission that travel would categorically not be funded. Applicants may submit special requests to allocate funds for travel if they can prove the travel is "directly incidental to the research".

Major items for the January meeting include: priorities for funding during the next fiscal year, revisions of the RFP, approval of Pettit's and Salmon's revised proposals, follow-up on other policy issues raised during this meeting.

The meeting adjourned at 4:15 p.m.

LMU:sm
ALUDCRC

APPENDIX C

Request for Competitive Sealed Proposals

Fiscal Year 1985-86

AVAILABILITY OF FUNDS FOR MEDICAL RESEARCH
ARIZONA DISEASE CONTROL RESEARCH COMMISSION
Request for Competitive Sealed Proposals

APPLICATION RECEIPT DEADLINE: OCTOBER 18, 1985

I. Background Information

The Arizona Disease Control Research Commission (Commission) was established by the Arizona Legislature and signed into law by Governor Bruce Babbitt in 1984. The Commission was created to advance medical research on diseases for which cures are currently not available.

The Commission will utilize funds available to the Disease Control Research Commission to contract for projects and services in the State of Arizona that can advance preclinical and clinical research into the causes, epidemiology, or diagnosis of human diseases. The Commission can also contract for research services in the formulation of medically acceptable methods for the treatment or prevention of human disease, including new drug discovery and development.

II. Research Goals and Scope

The goal of this RFP is to solicit research proposals in the following areas, which have been shown to greatly affect the health status of Arizona residents as determined by the Arizona Department of Health Services. The areas were selected by the Commission after an analysis of causes of death in the State of Arizona and with cognizance of alternative research funding sources already available within the State for certain disease categories (e.g. cardiac diseases, diabetes, and alcoholism). Applications must address one of the priority areas and must clearly state how the research project will benefit the residents of the State of Arizona.

Commission awards cannot be used for capital construction projects.

CURRENT PRIORITIES:

A. Malignant Neoplasms

B. Pulmonary Disease, including Chronic Obstructive Pulmonary Disease

C. Infectious Disease

D. Other - This area is restricted to research that does not fit other stated priority areas. Applicants in this category can apply only for small or intermediate program project funding. (See Section IIIA below) The Commission expects to fund small research projects in this category.

Total funding to be awarded for priority D is \$100,000 in FY 1985-86 and will be approximately 10% of the total funds available in any fiscal year.

III. Types of Projects

A. Small Projects. This project category is limited to budget requests of no more than \$15,000.

B. Intermediate Program Projects. This category includes one to two year projects with essentially one to three principal investigators involved in a project. Equipment requests for these projects cannot exceed 20% of the total proposed budget of direct costs.

C. Large Program Projects. This category includes three to five year projects consisting of multiple investigators from multidisciplinary backgrounds focusing on a common goal. Complete documentation of past and future productivity and potential is required for this category. Equipment requests for these projects cannot exceed 20% of the total proposed budget of direct costs.

IV. Institutional Approvals

All research proposals involving human or animal subjects must be submitted to the principal investigator's affiliated Institutional Human and/or Animal Subjects Committee (established in accord with Guidelines of the U.S. Department of Health and Human Services) prior to submission. Projects cannot be funded before Institutional approval is granted. The project budget must also be approved by an Institution's fiscal officer, if applicable. An indirect cost rate not to exceed 10% of the direct cost total budget may be added if approved by the Commission and the applicable institution.

V. Mechanisms of Support

The Arizona Legislature budgeted \$900,000 for 1985-1986, \$2,270,000 for 1986-1987, \$2,570,000 for 1987-1988, and additional monies until 1994. The regulation (Public Health and Safety, Chapter 3, Part 36-305) and policies that govern the research grant programs of the Public Health Services will prevail. The Commission is able to accept donations and Foundation funding in support of its research mission.

VI. Solicitation Period

The solicitation period under this RFP shall be from September 9, 1985 to October 18, 1985.

VII. Cost or Pricing Data

Cost or pricing data are required under this RFP.

VIII. Technical Assistance

1. Written Requests for Technical Assistance

Requests for technical assistance shall be in writing and shall be submitted to:

Lloyd F. Novick, M.D., Chairman
Arizona Disease Control Research Commission
1740 West Adams
Phoenix, AZ 85007

Commission response(s) to requests for technical assistance shall be in writing and mailed to each RFP recipient within five (5) working days of receipt.

2. Verbal Requests for Technical Assistance

Verbal requests for technical assistance shall not be allowed under this RFP.

IX. Amendments to RFP

Any and all amendments to this RFP shall be sent to all RFP recipients by registered mail, return receipt requested. The receipt shall serve as acknowledgment by RFP recipients of receipt of amendment(s).

X. Submission of Proposals

The original and 15 typewritten copies of completed proposals in response to this RFP must be submitted to:

Lloyd F. Novick, M.D., Chairman
Arizona Disease Control Research Commission
1740 West Adams
Phoenix, AZ 85007

No later than 5:00 PM on October 18, 1985

Proposals will not be accepted after the date and time specified above.

Evaluation Factors/Criteria (Continued)

- C. Offeror's financial stability, including a demonstration of sound fiscal and accounting procedures.
- D. Understanding of the problem including an ability to focus the study upon vital objectives; to anticipate major difficulties/problem areas, with recommended approaches for their resolution; and to develop a plan to accomplish the research objectives.
- E. Adequacy of facilities and staff, including personnel and equipment capable of supporting the proposed research, expertise and competence of staff in the techniques required for performance and in the field of proposed investigation.
- F. Responsiveness to the RFP.
- G. Relevance of the project to the State of Arizona and the health of its residents.
- H. Efforts to cost share the research proposed with other funding agencies, foundations, institutions or private donors.

XVI. Review Process

An initial review of the proposal will be conducted to ensure that it has been prepared and submitted in accordance with the requirements of the RFP, that the proposal is complete, and that all supporting documentation is attached. The initial review also will include a determination of the offeror's eligibility for Commission funding.

Following the initial review, the proposal will be peer-reviewed by scientific experts in appropriate fields as selected by the Commission. These individuals will be selected from sources such as the National Institutes of Health Public Advisory Group Membership, and only those reviewers residing outside Arizona will be selected. Applicants are to have no contact with the reviewers unless specifically requested by the Commission for on-site review. Peer reviewers will prepare a confidential written review of each proposal, as indicated in Section XV., Evaluation Factors/Criteria.

As specified in ARS 36-273.B.1, a subcommittee of the Commission shall be established to review and evaluate the proposals. The subcommittee will review the evaluations of the peer reviewers, and recommend proposals for funding to the full Commission.

The full Commission will make the final decision regarding contract award(s).

XVII. Cancellation

The Commission reserves the right to cancel this solicitation and any or all proposals may be accepted, modified or rejected in whole or in part.

XVIII. Notification of Contract Award

Each offeror shall be notified in writing of the Commission's decision to select or reject the proposal for a contract award.

Questions regarding the process or factors affecting selection shall be directed to:

Lloyd F. Novick, M.D., Chairman
Arizona Disease Control Research Commission
1740 West Adams
Phoenix, AZ 85007

Services shall be delivered under the contract beginning: January 1, 1986 and shall terminate on June 30, 1986 (for the first operational year of the Commission).

All contract awards made are subject to availability of funds.

XVIV. Financial Guidelines

- A. Source of Funds: 100% State funds
- B. Compensation Type: Fixed price establishes a set price per unit of measurement, as specified in the contract, eg. 60 minutes of staff time, a month of services, etc.
- C. Payment and Billing Method: Payments will be made upon receipt of contractor's approved invoice and/or expenditure report.
- D. An indirect cost rate not to exceed 10% of the direct cost total budget may be added if approved by the Commission and the applicable institutions.

SOLICITATION OR BID PROTEST

A protest shall be filed, and shall be resolved, in accordance with A.R.S. Title 41, Chapter 23, Article 9, and A.C.R.R. R2-7-901 through R2-7-937. A protest must be in writing and must be filed with the purchasing agency (Arizona Disease Control Research Commission) and the State Purchasing Administrator. A protest of a solicitation process must be received at the purchasing agency before the solicitation opening date. A protest of a proposed award or of an award must be filed within ten days after the protester knows or should have known the basis of the protest. A protest must include:

- A. The name, address and telephone number of the protester;
- B. The signature of the protester or its representative;
- C. Identification of the purchasing agency (Arizona Disease Control Research Commission) and the solicitation or contract number
- D. A detailed statement of the legal and factual grounds of protest including copies of relevant documents; and
- E. The form of relief requested.

The Arizona Procurement Code (A.R.S. Title 41, Chapter 23) and A.C.R.R. Title 2, Chapter 7, where applicable, are incorporated by reference herein and are made a part of this document as if they are fully set forth herein.

BUDGET CATEGORY

- A. Small Project
- B. Intermediate Program Project
- C. Large Program Project

Priority area* _____

Last Name _____

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

Application for Funding

PRINCIPAL INVESTIGATOR _____ Phone _____

INSTITUTION/AFFILIATION and ADDRESS _____

CO-INVESTIGATOR(S) (Please list all co-investigators and their institution/affiliation, and attach curriculum vitae for both the principal investigator and all co-investigators. List only pertinent references during the last five (5) years, which should include references relevant to the proposed project. Do not attach reprints or preprints.)

Name

Institution/Affiliation

*PRIORITY AREAS

- A. Malignant Neoplasms
- B. Pulmonary Disease
- C. Infectious Disease
- D. Other (Project Categories A and B Only)

Priority area _____

Last Name _____

Please confine responses to this page.

SHORT TITLE OF PROPOSED RESEARCH

RESEARCH ABSTRACT (Briefly summarize your research project in lay language.)

SIGNIFICANCE OF PROPOSED RESEARCH (State succinctly the importance of the project to disease control research in the State of Arizona, the originality of the approach and the expected contribution.)

Priority Area _____
Last Name _____

PLAN OF PROCEDURE (Experimental plan of what is to be done and its relation to the above statement; point out innovative features and annotate literature references which are particularly pertinent. The Plan of Procedure should consist of no more than 10 typewritten, single spaced pages for Small and Intermediate program projects, and no more than 20 single spaced pages for Large program projects. The Commission reserves the right to reject proposals that exceed the specified page limits.)

RESEARCH INVOLVING HUMAN OR ANIMAL SUBJECTS

_____ NO

_____ YES - Approved by Submitting Institution.

_____ YES - No Review has Occurred.

_____ YES - Pending Review by Submitting Institution.

The investigator must submit documentation that the affiliated institution has approved the use of human or animal subjects by its standing committee. The research will not be funded without approval from an affiliated institution.

Priority Area _____
Last Name _____

DETAILED BUDGET AND JUSTIFICATION (Continued)

TOTALS

TRAVEL

PATIENT CARE COSTS (Itemize into inpatient and outpatient categories) \$ _____

ALTERATIONS AND RENOVATIONS TO SPACE (Itemize by category) \$ _____

OTHER EXPENSES (Itemize by category) \$ _____

TOTAL DIRECT COSTS \$ _____

INDIRECT COSTS (Must not exceed 10% of budget request. Please justify.) \$ _____

TOTAL INDIRECT COSTS \$ _____

TOTAL - ENTIRE BUDGET PERIOD (Includes indirect costs). \$ _____

Priority area _____
 Last Name _____

SUMMARY BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD

BUDGET CATEGORY TOTALS	1st Budget Period (1/86-6/86 From pg. 5)	2nd Budget Period FY 86-87	3rd Budget Period FY 87-88	4th Budget Period FY 88-89	5th Budget Period FY 89-90
PERSONNEL (Salary and fringe benefits)					
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES					
TRAVEL					
PATIENT CARE COSTS Inpatient Outpatient					
ALTERATIONS & RENOVATIONS					
OTHER EXPENSES					
TOTAL DIRECT COSTS					
TOTAL INDIRECT COSTS (Not to exceed 10% of request)					
<u>TOTAL(S) FOR ALL PERIODS</u>	\$	\$	\$	\$	\$

Priority area _____
Last Name _____

OTHER SUPPORT (List both external and internal sources, periods and direct cost amounts of all other support received or requested (1) for this research and (2) for other research; clearly identify other requests which duplicate this one.)

Total Other Support \$ _____

Signature of Principal Investigator

Date

Priority Area _____
Last Name _____

SUBMITTED BY _____
Name of institution adopting and assuming responsibility for the above project,
believing that the principal investigator is qualified to conduct the project, and
accepting the Conditions of the Award, if an award should be granted.

Name and position of authorized officer

Signature of authorized officer

Date

RETURN: Signed original and fifteen legible, typewritten copies.

APPENDIX D

Description of Proposals Submitted

Arizona Disease Control Research Commission

Fiscal Year 1985-86

One hundred fifty-six proposals were submitted, totaling over five million dollars in requests for funding. There was approximately \$850,000.00 available for awards.

<u>Priority Area</u>	<u>#</u>	<u>% Total</u>	<u>Approximate Amount Requested</u>
"Other"	81	52%	\$1,995,009.00
Malignant Neoplasm	38	24%	1,983,059.00
Pulmonary Disease	18	12%	464,091.00
Infectious Disease	19	12%	642,339.00
TOTAL	156	100%	\$5,084,498.00

<u>Category</u>	<u># Submitted</u>
Small (\$15,000 and under)	91
Intermediate (\$100,000 and under)	63
Large	2

<u>Institution</u>	<u># Submitted</u>	<u>%Total Submitted</u>
University of Arizona and University of Arizona Health Sciences Center (Tucson)	86	56%
Arizona State University (Tempe)	27	17%
Barrow Neurological Institute St. Joseph's Medical Center (Phoenix)	7	4%
Northern Arizona University (Flagstaff)	8	5%
*Other:	28	18%
	<hr/>	<hr/>
TOTAL	156	100%

* Veterans Administration (Tucson)	3
Genetics Center (Phoenix)	1
Pima County (Tucson)	2
Scottsdale Memorial Hospital (Scottsdale)	1
Maricopa County (Phoenix)	1
Arizona Department of Health Services (Phoenix)	1
St. Lukes Hospital (Phoenix)	3
Humana Hospital (Phoenix)	1
Individuals (Sun City)	2
Tuba City (Tuba City)	1
Phoenix Childrens' Hospital (Phoenix)	2
Southwest Biomedical Research Institute (Phoenix)	2
St. Joseph's Hospital (Phoenix)	1
Phoenix Memorial Hospital (Phoenix)	1
Osteoporosis and Bone Center (Phoenix)	1
Alexander Institute (Phoenix)	1
Lincoln Dialysis Center (Phoenix)	1
Valley View Community Hospital (Phoenix)	2
Orthopedic Surgeons (Phoenix)	1

APPENDIX E

Description of Proposals Approved

for funding

Arizona Disease Control Research Commission

1985

Twenty-four projects were funded totaling \$851,013.

<u>Priority Area</u>	<u># of Awards</u>	<u>% Total Awards</u>	<u>Amount Awarded</u>	<u>% Total Funding Amount</u>
Malignant Neoplasms (Cancer)	10	42%	\$502,500	59%
"Other"	8	33%	160,978	19%
Infectious Disease	4	17%	113,359	13%
Pulmonary Disease	2	8%	74,176	9%
TOTAL	24	100%	851,013	100%

<u>Institution</u>	<u># Funded</u>	<u>% Total</u>
University of Arizona and University of Arizona Health Sciences Center (Tucson)	15	63%
Arizona State University (Tempe)	4	17%
Barrow Neurological Institute St. Joseph's Hospital (Phoenix)	3	12%
Pima County Health Department (Tucson)	1	4%
Northern Arizona University (Flagstaff)	1	4%
TOTAL	24	100%

<u>PRINCIPAL INVESTIGATOR</u>	<u>INSTITUTION</u>	<u>TITLE OF PROPOSAL</u>	<u>\$ AMOUNT</u>
Emmanuel Akporiaye Ph.D.	Northern Arizona University Department of Biological Sciences Flagstaff, Arizona 86011	"Generation of T-Lymphocytes High Anti-Tumor Activity"	\$32,780
Harris Bernstein Ph.D.	University of Arizona Department of Microbiology College of Medicine Tucson, Arizona 85724	"The DNA Damaging Activity of Bile Acids in Colon Tissue: Relationship to Colon Cancer"	\$14,685
Raymond F. Carmody M.D.	University of Arizona Department of Radiology Health Sciences Center Tucson, Arizona 85724	"Magnetic Resonance Imaging for Spinal Cord Compression due to Metastasis"	\$17,897
L. Philip Carter, M.D.	Barrow Neurological Institute 350 W. Thomas Road Phoenix, Arizona 85013	"Thrombolytic Treatment of Cerebral Ischemia"	\$9,200
Richard C. Dart, M.D.	University of Arizona Section of Emergency Medicine Tucson, Arizona 85724	"Delivery of Rattlesnake Venom Across the Skin"	\$4,362
William J. Dorson, Ph.D.	Arizona State University Department of Chemical and Bio Engineering Tempe, Arizona 85287	Extracorporeal Detoxification of Hyperbilirubinemia"	\$13,464
John Galgiani, M.D.	University of Arizona College of Medicine Tucson, Arizona 85724	"Purification and Application of Antigens from <i>Coccidioides Immitis</i> "	\$53,600
Stanley Goldberg, M.D.	University of Arizona Department of Pediatrics Health Sciences Center Tucson, Arizona 85724	"Human Cardiac Teratogenesis of TCE"	\$19,589

<u>PRINCIPAL INVESTIGATOR</u>	<u>INSTITUTION</u>	<u>TITLE OF PROPOSAL</u>	<u>\$ AMOUNT</u>
Eric J. Guilbeau, Ph.D.	Arizona State University Department of Chemical and Bio Engineering Tempe, Arizona 85287	"Glucose Sensor for Treatment of Diabetetes	\$13,570
Peter Hurd, Ph.D.	University of Arizona College of Pharmacy Tucson, Arizona 85724	"Training Caregivers to Detect Medication Problems in the Elderly"	\$14,952
Chester R. Leathers, Ph.D.	Arizona State University Department of Botany and Microbiology Tempe, Arizona 85287	"Coccidioidomycosis: Improved Diagnostic Techniques	\$20,576
Norman Levine, M.D.	University of Arizona Department of Dermatology College of Medicine Tucson, Arizona 85724	"Radiofrequency Hyperthermia in the Treatment of Skin Cancer"	\$16,274
Thomas J. Lindell, Ph.D.	University of Arizona Biosciences West Building Tucson, Arizona 85721	"Study of Genes Related to Characteristics and Properties of a Cancer Cell"	\$12,346
Michael Mayersohn, Ph.D.	University of Arizona College of Pharmacy Tucson, Arizona 85721	"Pentamidine Disposition Kinetics in Dogs"	\$6,822
Patricia Nolan, M.D.	Pima County Health Department 150 W. Congress Tucson, Arizona 85701	"Epidemiology of Shigellosis Infections in Pima County"	\$18,537
George R. Pettit, Ph.D.	Arizona State University Cancer Research Institute Physical Sciences C-Wing Tempe, Arizona 85287	"Discovery and Development of New Anticancer Drugs"	\$80,000

<u>PRINCIPAL INVESTIGATOR</u>	<u>INSTITUTION</u>	<u>TITLE OF PROPOSAL</u>	<u>\$ AMOUNT</u>
Findlay E. Russell, M.D.	University of Arizona College of Pharmacy Tucson, Arizona 85724	"A Human Antitoxin, Antivenin"	\$11,644
Sydney E. Salmon, M.D.	Arizona Cancer Center University of Arizona Tucson, Arizona 85724	"Arizona Cancer Center Research Program"	\$315,000
Andrew G. Shetter, M.D.	Barrow Neurological Institute 350 W. Thomas Road Phoenix, Arizona 85013	"Intraventricular Bethanecol Infusion in the Treatment of Alzheimers Disease"	\$14,850
Robert F. Spetzler, M.D.	Barrow Neurological Institute 350 W. Thomas Road Phoenix, Arizona 85013	"Therapeutic Management of Acute Stroke"	\$44,607
Charles R. Sterling, Ph.D.	University of Arizona Department of Veterinary Services 202 Building 90 Tucson, Arizona 85724	"Giardiasis and Cryptosporidiosis in Arizona"	\$36,564
Robert G. Volz, M.D.	University of Arizona Health Sciences Center Orthopedic Surgery Tucson, Arizona 85724	"The Efficacy of Treatment of Infected Orthopedic Implants with Electrical Current"	\$14,740
Sheldon Weiner, M.D.	University of Arizona Health Sciences Center Department of Obstetrics and Gynecology Tucson, Arizona 85724	"Topical Interferon in the Treatment of Cervical Dysplasia"	\$13,517
Marlys H. Witte, M.D.	University of Arizona Department of Surgery College of Medicine Tucson, Arizona 85724	"Association of Kaposis Sarcoma with AIDS"	\$51,436

APPENDIX F

Arizona Disease Control Research Commission
Contract and Workstatement

1985

ARIZONA DISEASE CONTROL RESEARCH COMMISSION

1740 West Adams Street
Phoenix, Arizona 85007

CONTRACT NUMBER

Page 1

RESEARCH SERVICE CONTRACT

1. SOURCE OF FUNDS <input type="checkbox"/> State <input type="checkbox"/> Contractor's Share		2. COMPENSATION TYPE Fixed Price	3. CONTRACT AMOUNT \$ 4. EFFECTIVE DATE 5. EXPIRATION DATE
6. BILLING METHOD		7. PAYMENT METHOD Quarterly Advancement	
8. ADCRC PROJECT CHAIRMAN LINDA H. UDALL		9. PROJECT TITLE	
10. CONTRACTOR - Name, Address		11. SUBCONTRACTOR(S) <input type="checkbox"/> Yes <input type="checkbox"/> No	
		12. ADCRC AUTHORITY TO CONTRACT FOR SERVICES SPECIFIED HEREIN ARS 36-271	
13. BUDGET CATEGORY <input type="checkbox"/> Small Project <input type="checkbox"/> Intermediate Program Project <input type="checkbox"/> Large Program Project		14. PRIORITY AREA <input type="checkbox"/> Malignant Neoplasms <input type="checkbox"/> Pulmonary Disease <input type="checkbox"/> Infectious Disease <input type="checkbox"/> Other	

15. CONTRACTOR AGREES to perform all the services set forth in the attached Work Statement for the consideration stated herein. The rights and obligations of the parties to this Contract shall be subject to and governed by the Special Provisions and the General Provisions. To the extent of any inconsistency between the Special Provisions and the General Provisions and any specifications or other provisions which are made a part of this contract by reference or otherwise, the Special Provisions and the General Provisions shall control. To the extent of any inconsistency between the Special Provisions and the General Provisions, the Special Provisions shall control. Amendments signed by each of the parties and attached hereto are hereby adopted by reference as a part of this Contract as if fully set out herein.

NAME OF CONTRACTOR	ARIZONA DISEASE CONTROL RESEARCH COMMISSION
SIGNATURE OF AUTHORIZED INDIVIDUAL By	SIGNATURE OF AUTHORIZED INDIVIDUAL By
TYPED NAME	TYPED NAME LLOYD F. NOVICK, M.D.
TITLE	TITLE CHAIRMAN
DATE	DATE

COVER PAGE

1. DEFINITIONS

As used throughout these General Provisions, the following terms shall have the meaning set forth:

- a. "Contractor" means the person, firm, or organization performing the services or delivering the items described in this Contract.
- b. "State" means the State of Arizona.
- c. "Commission" means the Arizona Disease Control Research Commission or his duly authorized representative.
- d. "Chairman" means the Arizona Disease Control Research Commission Chairman or his duly authorized representative.
- e. "Subcontract" means any contract between the original Contractor and a Third party for the provision of items or services which the original Contractor has himself contracted with the Commission to perform, except purchase orders for standard commercial equipment, products or services.
- f. "Service Recipient" means individual persons who are eligible for services provided by the Commission or by an authorized Contractor of the Commission.
- g. "Project Chairman" means the person designated to represent the Commission in the program administration of this Contract.
- h. "Special Provisions" means those provisions of this Contract which modify the Contract Provision. If the Contract Provisions and Special Provisions conflict, the Special Provisions shall govern.
- i. "Work Statement" means those provisions of this Contract which delineate the scope and manner of the specific services to be performed and/or describe the items to be supplied in the performance of this Contract. If the provisions of the Work Statement conflict with the Special Provisions and/or the General Provisions, the terms of the Work Statement shall govern.

2. GENERAL REQUIREMENTS

- a. Intergovernmental agreements entered into pursuant to A.R.S. 11-951 et seq shall become effective on the date filed with the Secretary of State or at a later date as specified in the contract. All other contracts shall become effective on the date executed by the Chairman or at a later date as specified in the contract.
- b. This Contract shall be construed in accordance with Arizona law and any legal action thereupon shall be initiated in an appropriate court of the State of Arizona or, in the event the Contractor is a reservation Indian or Indian tribe, in the United States District Court.
- c. The Contractor shall obtain and maintain all licenses, permits and authority necessary to do business and render services under this Contract, and shall comply with all laws regarding unemployment insurance, disability insurance and workmen's compensation.
- d. The parties hereto agree that the Contractor shall be deemed an independent contractor in the performance of this Contract, and shall not be considered an officer, employee or agent of the State.

GENERAL PROVISIONS

- e. Except for persons employed by the Board of Regents or a unit thereof, no individual employed by the State on a full-time basis shall be admitted to any share of this Contract, or any benefit that may arise therefrom.

3. OTHER CONTACTS

The Commission may perform additional work related to this Contract or award other contracts for such work. The Contractor shall cooperate fully with such other contractors and/or State employees in the scheduling of and coordination of its own work with such additional work. The Contractor shall afford other contractors reasonable opportunity for the execution of their work and shall not commit or permit any act which will interfere with the performance of work as scheduled by any other contractor or by State employees. This section shall be included in all subcontracts and will be included in the contracts of all contractors with whom this Contractor will be required to cooperate. The Commission shall equitably enforce this section as to all contractors, to prevent the imposition of unreasonable burdens on any contractor.

4. SUBCONTRACTS AND ASSIGNMENTS

- a. Unless otherwise agreed by the terms of this Contract, the Contractor shall not subcontract with any other party for the furnishing of any of the work or services contracted for herein without the prior written approval of the Commission. When authority of subcontract is granted, the Contractor agrees to utilize written subcontracts drawn in conformity with Federal and State laws and regulations which are appropriate to the service or activity covered by the subcontract and which shall include all of the general provisions set forth herein (except paragraphs 11, 12, and 13) which shall apply with equal force to the subcontract as if the Subcontractor were the Contractor referred to herein. The Contractor is responsible for contract performance whether or not subcontractors are used. The Contractor shall submit a copy of each subcontract to the Commission 30 days prior to its effective date.
- b. No rights or obligations of the Contractor under this Contract shall be assigned without the prior written consent of the Commission. The Contract is voidable and subject to immediate cancellation by the Chairman upon the Contractor becoming insolvent, or filing proceedings in bankruptcy or reorganization under Title XI, United States Code.

5. OWNERSHIP OF INFORMATION

Title to all reports, information, data, computer data elements and software prepared by the Contractor in performance of this Contract shall vest in the State. Subject to applicable State and Federal laws and regulations, the State shall have full and complete rights to reproduce, duplicate, disclose and otherwise use all such information.

6. CONFIDENTIALITY OF RECORDS

The Contractor shall establish and maintain procedures and controls that are acceptable to the Commission for the purpose of assuring that no information contained in its records or obtained from the Commission or from others in carrying out its functions under this Contract shall be used or disclosed by it, its agents, officers, or employees, except as is essential to the performance of duties under this Contract. Persons requesting such information should be referred to the Commission. The Contractor also agrees that any information pertaining to service recipients shall not be divulged, other than to employees or officers of Contractor as is required for the performance of duties under the contract, except upon the prior written consent of the Commission.

7. REPORTS AND RECORDS

All contractors, agree:

- (1) To submit all reports and invoices as specified in the Work Statement of this Contract.
- (2) The Contractor and any Subcontractors shall preserve and make available all records for a period of three years from the date of final payment under this Contract or until resolution of an audit by the Commission, whichever shall first occur, and for such period as is required by any other paragraph of this Contract including the following:
 - (a) If this Contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of three years from the date of any such termination.
 - (b) Records which relate to disputes, litigations or the settlement of claims arising out of the performance of this Contract, or to cost and expenses of this Contract as to which exception has been taken by the Chairman, shall be retained by the Contractor until such appeals, litigations, claims or exceptions have been disposed of.

8. INDEMNIFICATION

- a. Contractor shall indemnify, defend and save harmless the State and/or any of its agents, officials and employees, from any and all claims, demands, suits, actions, proceedings, loss, costs, and damages of every kind and description, including any attorney's fees and/or litigation expenses, which may be brought or made against or incurred by the State on account of loss of or damage to any property or for injuries to or death of any person, caused by, arising out of, or contributed to, in whole or in part, by reasons of any alleged act, omission, professional error, fault, mistake; or negligence of Contractor, its employees, agents, or representatives in connection with or incident to the performance of this Agreement, or arising out of Workmen's Compensation claims Unemployment Compensation claims or Unemployment Disability Compensation claims of employees of Contractor and/or its subcontractors or claims under similar such laws or obligations. Contractor's obligation under this Section shall not extend to any liability caused by the sole negligence instrumentality or subdivision thereof, or a reservation Indian or Indian tribe.
- b. The Contractor shall provide and maintain, and cause its subcontractors to provide and maintain, the following minimum insurance coverage:
 - (1) Comprehensive general liability insurance with a minimum combined single limit of one million dollars (\$1,000,000) each occurrence. The policy shall include coverage for bodily and personal injury, broad form property damage, blanket contractual, contractor's protective and products and completed operations.
 - (2) Comprehensive automobile liability insurance with a combined single limit for bodily injury and property damage of not less than one million dollars (\$1,000,000) each occurrence with respect to Contractor's vehicles (whether owned, hired, non-owned), assigned to or utilized in the performance of this Contract.
- c. Additional insurance coverage may be required at the Commission's discretion where the nature of the services to be performed are deemed to be extra hazardous in nature.
- d. The policies required by sections b (1) and (2) shall name the State of Arizona, its agents, officials and employees as additional insured and shall specify that the insurance afforded Contractor shall be primary insurance and that any insurance coverage carried by the State, the Commission or its employees shall be excess coverage and not contributory insurance to that provided by the Contractor. Said policy shall contain a severability of interests provision.

- e. Failure on the part of the Contractor to procure and maintain the required liability insurance and provide proof thereof to the Commission within thirty (30) days following the commencement of a new policy period, shall constitute a material breach of the contract upon which the Commission may immediately terminate this agreement. Prior to the effective date of this Contract, the Contractor shall furnish the Commission with copies of the State of Arizona Certificate of Insurance (RM-7200.1), drawn in conformity with the above insurance requirements. The State of Arizona reserves the right to request and receive certified copies of any or all of the above policies and/or endorsements.

9. WARRANTY

Contractor warrants that:

- a. All services shall be performed in conformity with the requirements of this Contract by qualified personnel in accordance with generally recognized standards.
- b. All non-service items furnished pursuant to this Contract shall be free from defects and shall conform to contract requirements. Any items determined by the Commission to be in nonconformity with this warranty shall be repaired or replaced, at the Commission's option and at the Contractor's expense, for up to one year following the completion or termination of this Contract.

10. WAIVERS

No condition or requirement contained in or made a part of this Contract shall be waived or modified without an approved amendment to this Contract.

11. DISPUTES

- a. In the event of a dispute concerning a question of fact arising under this Contract which cannot be resolved by the Project Chairman and the Contractor, the aggrieved or dissatisfied person may file a request for review. Within thirty days the Chairman shall hold a hearing presided over by a hearing officer who may be the Chairman or any qualified person or panel whom the Chairman may appoint. Within five days after filing the request for hearing, the complaining person shall file the notice specified by A.R.S. 41-1009 with the hearing officer. The hearing officer shall rule on all motions, hold conferences for the purpose of clarifying procedural steps or legal or factual issues, conduct the hearing, grant continuances and otherwise rule on procedural matters and regulate the course and manner of the hearing. All hearing shall be recorded. All testimony shall be under oath or affirmation. Within twenty days after the conclusion of the hearing, the hearing officer shall prepare and circulate written findings of fact and conclusions of law and a recommended decision. Each of the parties shall have five days in which to respond. The hearing officer may revise or supplement his original findings, conclusions and recommended decision in light of responses made or may submit his findings, conclusions and recommended decisions and a copy of all responses to the Chairman along with a legible or audible copy of the record and all documentary evidence. The Chairman shall issue his findings of fact, conclusions of law and decision in writing and mail or otherwise furnish a copy thereof to Contractor. This decision shall be subject to review pursuant to final decision of a dispute, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Chairman's decision.

GENERAL PROVISIONS

- b. However, paragraph a. shall not preclude consideration by the Chairman of the questions of law in connection with decisions pursuant to paragraph a., provided that nothing in this Contract shall be construed as making final the decision of the Chairman on a question of law.
- c. The parties agree to use arbitration to resolve disputes where the sole relief sought is monetary damages. If the parties cannot otherwise agree upon an arbitrator, the services of the American Arbitration Association shall be used and the A.A.A. Commercial Arbitration rules shall apply; a single arbitrator shall be selected by alternatively striking names from a list of arbitrators furnished by the A.A.A. The parties agree to waive oral hearings and specifically agree that the arbitrator shall decide any claim solely on the record made and the evidence received at the administrative hearing. The parties further agree that each shall bear its own costs and that any costs assessed by the arbitrator shall be equally divided between the parties to the claim.
- d. In the event that all parties to this agreement are represented by the State Attorney General's Office, paragraphs a-c shall not apply. The parties, however, do agree to utilize arbitration to resolve any disputes arising under this Agreement.

12. TERMINATION OF CONTRACT

The Commission or the State may terminate this Contract under any of the conditions following:

- a. The Chairman, in addition to other rights set forth elsewhere in the contract, reserves the right to terminate this Contract in whole or in part without cause effective 30 days after mailing written notice of termination by certified mail, return receipt requested, to the Contractor.
 - (1) In the event of termination as provided in this section, the Contractor shall stop all work as specified in the notice of termination and immediately notify all subcontractors in writing to do the same.
 - (2) Contractor shall be paid the contract price for all services and items completed. In addition, Contractor will be paid its reasonable actual costs for work in progress as determined by generally accepted accounting principles and practices. Upon such termination, the Contractor shall deliver to the Commission a complete set of all documents, programs and other information described in the contract.
- b. The Chairman may, by written notice to the Contractor, also terminate this Contract if it is found, after notice and hearing, by the Chairman, that gratuities in the form of entertainment, gifts, or otherwise were offered or given by the Contractor, or any agent or representative of the Contractor, to any officer or employee of the State with a view toward securing a contract or securing favorable treatment with respect to the awarding or amending or the making of any determinations with respect to the performing of such contract; provided, that the existence of the facts upon which the Chairman makes such findings shall be in issue and may be reviewed in any competent court. If the contract is terminated under this section, unless the Contractor is a governmental agency, instrumentality or subdivision thereof, or a reservation Indian or Indian tribe, the Commission shall be entitled, by way of penalty, to exemplary damages in the amount of three times the costs incurred by the Contractor in providing any such gratuities to any such officer or employee, in addition to any other damages to which it may be entitled by law.

- c. The State of Arizona may cancel this Contract without penalty or further obligation to the State pursuant to A.R.S. 38-511, if any person significantly involved in initiating, negotiating, securing, drafting or creating this Contract on behalf of the State of Arizona is or becomes at any time, while this Contract or any extension of this Contract is in effect, an employee of any other party to this Contract. Cancellation shall be effective when written notice from the Governor is received by all parties to this Contract unless the notice specifies a later time.

13. DEFAULT

- a. The Chairman, in addition to other rights set forth elsewhere in the contract, may at any time terminate this Contract in whole or in part if the Chairman determines that the Contractor has failed to perform any requirements of this Contract or has failed to make satisfactory progress toward performance. In such case, the Chairman shall transmit notice of default to the Contractor by certified mail, return receipt requested, and this Contract shall be terminated effective upon receipt thereof by the Contractor, or such later date as is specified in the notice.
- b. The Contractor shall continue the performance of this Contract to the extent not terminated under the provisions of this section.
- c. In the event the Chairman terminates this Contract in whole or part as provided in this section, the Chairman may procure, upon such terms and in such manner as it may deem appropriate, services similar to those so terminated, and unless the Contractor is a governmental agency, instrumentality or subdivision thereof, or a reservation Indian or Indian tribe, it shall be liable to the Commission for any excess costs incurred by the Commission in obtaining such similar services.
- d. Except with respect to defaults of Subcontractors, the Contractor shall not be liable for any excess costs if the failure to perform the contract arises out of causes beyond the control and which occur without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the State or Federal Government in either their sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather. If the failure to perform is caused by the default of a subcontractor, and if such default arises out of causes beyond the control of both the Contractor and Subcontractor and without the fault arises out of causes beyond the control of both the Contractor and Subcontractor and without the fault or negligence of either, the Contractor shall not be liable for any excess costs for failure to perform, unless the services to be furnished by the Subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.
- e. If this Contract is terminated as provided herein, the Chairman, in addition to any other rights provided in this section, may require the Contractor to transfer title to and deliver to the State, in the manner and to the extent directed by the Chairman, such partially completed reports or other documentation as the Contractor has specifically produced or specifically acquired for the performance of such part of this Contract as has been terminated. Payments for completed reports and other documentation delivered to and accepted by the Chairman shall be at the contract price. Payment for partially completed reports and other documentation delivered to and accepted by the Chairman shall be in an amount agreed upon by the Contractor and the Chairman.

14. NON-DISCRIMINATION

The Contractor shall comply with Title VII of the Civil Rights Act of 1964, as amended, the Age Discrimination in Employment Act of 1975, and State Executive Order No. 75-5 which mandates that all persons, regardless of race, color, religion, sex, age, national origin or political affiliation, shall have equal access to employment opportunities. The Contractor shall comply with section 503 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination in the employment or advancement in employment of qualified persons because of physical or mental handicap. The contract shall comply with Title VI of the Civil Rights Act of 1964, which prohibits the denial of benefits or participation in contract services on the basis of race, color, or national origin. The Contractor shall comply with the requirements of Section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of handicap, in delivering contract services.

15. ASSIGNMENT OF OVERCHARGES

The Contractor, The Commission and the State recognize that in actual economic practice overcharges resulting from antitrust violations are in fact borne by the purchaser. Therefore, the contractor hereby assigns to the Commission and the State any and all claims for such overcharges.

16. CONTRACT PAYMENTS

- a. Payments made by the Commission to the Contractor pursuant to this Contract are conditioned upon the availability to the Commission of funds authorized for expenditure in the manner and for the purpose herein. The Commission shall not be liable for any purchases and/or contracts entered into by the Contractor in anticipation of such funding.
- b. Payments made by the Commission to the Contractor are conditioned upon receipt of applicable, accurate and complete reports to be submitted by the Contractor.
- c. If the Contractor is in any manner in default in the performance of any obligation under this Contract, or if audit exceptions are identified, the Commission may, at its option and in addition to other available remedies, either adjust the amount of payment or withhold payment until satisfactory resolution of the default or exception. The Contractor shall have the right to written notice of the Commission's action in adjusting the amount of payment or withholding payment. Under no circumstances shall the Commission authorize payment to the Contractor that exceeds an amount specified in the contract without an approved amendment to the contract. The Commission may, at its option, withhold final payment under the contract until receipt of all final reports and deliverables.

17. RECOUPMENT OF CONTRACT PAYMENTS

- a. **Unexpended Funds**
Any unexpended Commission funds that have been advanced to the Contractor and remain in its possession at the end of the contract period, or at the time of termination of the contract, shall be refunded to the Commission within 45 days thereafter.
- b. **Unacceptable Expenditures**
The Contractor agrees to reimburse the Commission for all contract funds expended which are determined by the Commission or the Auditor General not to have been disbursed by the Contractor in accordance with the terms of this Contract.

18. MANAGEMENT OF FUNDS

All funds received by the Contractor pursuant to this Contract shall be separately accounted for in accordance with an accounting system acceptable to the Commission. For all contracts, other than those designated as "outside professional" the practices, procedures and standards specified in and required by the Accounting and Auditing Procedures Manual for Arizona Department of Health Services Funded Programs shall be used by the Contractor in the management of contract funds and by the Commission when performing a contract audit.

19. ALLOWABLE EXPENDITURES

Expenditure of funds advanced, or qualifying for reimbursement, pursuant to this Contract shall be made by the Contractor only for the following:

- a. Services or materials approved or appropriated for, and used in, the performance of services herein agreed to be provided.
- b. Services or materials which are received by the Contractor:
 - (1) During the contract term for which the funds are made available; and
 - (2) On or after the effective date of the contract or, with regard to funds made available during a contract term by an amendment to the contract, on or after the effective date of that amendment; and
 - (3) On or before the termination date.
- c. Account classifications shown on the approved contract budget page.

20. VISITATION AND INSPECTION

- a. Commission representatives shall, at any reasonable time during the term of this Contract, be entitled to review the Contractor's facilities, its program operation and those of its records which pertain to the program funded by this Contract.
- b. The Contractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access to the Contractor's facilities and the right to examine books, documents, and records of the Contractor involving transactions related to this Contract.
- c. The Contractor further agrees to include in all his subcontracts hereunder, if any, a provision to the effect that the Subcontractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access to the Subcontractor's facilities and the right to examine any books, documents and records of the Subcontractor, involving transactions related to the subcontract and that such books, documents and records shall not be disposed of except as provided herein.

21. RECOGNITION OF COMMISSION SUPPORT

The Contractor agrees to give recognition to the Commission for its support of the program when publishing program material or releasing program related public information.

22. TITLE TO EQUIPMENT

- a. The title to any and all equipment acquired through the expenditure of funds from the Commission pursuant to this Contract shall remain in the Commission. The acquisition of any such property must be specifically authorized in advance by the Project Chairman and for property such as a motor vehicle which has a document evidencing title, the title shall be acquired in the name of the Commission. When this Contract is terminated, the disposition of all such property shall be determined by the Commission.
- b. The Contractor agrees to exercise reasonable control over all equipment purchased with contract funds. All equipment lost, stolen, rendered unuseable or no longer required for program operation must be reported immediately to the Commission for disposition instructions. The Contractor shall conduct an annual physical inventory of equipment, using forms supplied by the Commission, within 60 days after the end of the contract term, or at the time of termination of this Contract.

23. INFRINGEMENT OF PATENTS AND COPYRIGHTS

- a. The Contractor, at his own expense, will defend any claim or suit which may be brought against the State for the infringement of United States patents or copyrights arising from the Contractor's or Commission's use of any equipment, materials, or information prepared or developed in connection with performance of this Contract and in any suit will satisfy any final judgment for such infringement. The Commission will give the Contractor written notice of such claim or suit and full right and opportunity to conduct the defense thereof, together with full information and all reasonable cooperation.
- b. If principles of governmental or public law are involved, the State may participate in the defense of any such action, but no costs or expenses shall be incurred for the account of Contractor without written consent.
- c. If in Contractor's opinion the equipment, materials or information mentioned in paragraph a. above is likely to or does become the subject of a claim of infringement of a United States patent or copyright, then without diminishing Contractor's obligation to satisfy any final award, Contractor may, with the Chairman's written consent, substitute other equally suitable equipment, materials and information, or at Contractor's option and expense, obtain the right for Contractor or the Commission to continue the use of such equipment, materials and information.

24. NOTICES

Whenever notice is required pursuant to the terms of this Contract, said notice shall be in writing, shall be delivered in person or by certified mail, return receipt requested, and shall be directed to the persons and addresses specified for such purpose in Section D of the Work Statement (ADHS/ADM/CAS-353) or to such other persons and/or addresses as either party may designate to the other party by written notice.

CONTRACT NUMBER

SPECIAL PROVISIONS

Page 11

1. The total budget for any category may not be reduced by more than 15% during a contract year without submission of a written request to the Commission prior to the transfer of funds.

PAYMENT AND BUDGET PAGES

SOURCE OF FUNDS

- Federal
- State
- Contractor's Share

COMPENSATION TYPE

- Fixed Price
- Cost Reimbursement

PAYMENT AND BILLING METHOD

Payment Method	Schedule of Estimated Case Requirements	Billing Method
<input checked="" type="checkbox"/> Advancement	No	Encumbrance Authorization
<input type="checkbox"/> Modified Monthly	Yes	Monthly Expenditure
<input type="checkbox"/> Monthly Advancement Reimbursement	Yes	Quarterly Expenditure Report
<input type="checkbox"/> Reimbursement	No	Monthly Expenditure
<input type="checkbox"/> Weekly Advance	Yes	Monthly Expenditure

COMPENSATION TYPE

- a. Fixed Price - establishes a set price per unit or measurement as specified in the contract.
- b. Cost Reimbursement provides for reimbursement to the contractor for actual costs incurred, as outlined in the contract, in delivering services under the contract.

PAYMENT AND BILLING METHOD

- a. Advancement - 100% State Funds
Payments will be made as outlined in the contract.
- b. Modified Monthly Reimbursement - 100% Federal Funding
100% State Funding
Federal and State (Mixed)
 - (1) The Contractor will prepare a schedule of estimated cash requirements for each month of the contract.
 - (2) Monthly payments will be processed by the Commission by the twenty-fifth (25th) of each month based upon the schedule of estimated cash requirements.
 - (3) Contractor will prepare monthly actual expenditure reports and submit to the Commission by the fifteenth (15th) of the following month.
 - (4) Each following month's payment will be adjusted for any variance between the previous month's estimated advance and actual expenditure.
- c. Monthly Advancement - 100% State Funding
Federal and State (Mixed Funding)
 - (1) Contractor will prepare a schedule of projected monthly cash requirements for the contract period.
 - (2) The Commission will make the first (1st) and second (2nd) monthly advance payments based on the schedule of monthly cash requirements.
 - (3) Contractor will report actual monthly expenditures by the fifteenth (15th) of each following month.
 - (4) Each advance payment made following receipt of the monthly expenditures report will be based on the schedule of monthly cash requirements adjusted for any variance between the amount advanced and actual expenditures of the reporting month.

CONTRACT NUMBER

Page 13

PAYMENT AND BUDGET PAGES

NOTE: For mixed funded contracts, as a matter of Commission policy, state funds will be used for the first month's advance; subsequent advances with federal funds will be considered as reimbursement on an estimated basis.

d. Monthly Advancement/Reimbursement - Federal and State (Mixed) Funding

- (1) Each contractor will estimate each month's funding requirements prior to the beginning of the contract period. The monthly estimates should closely approximate the prior year's actual monthly expenditures on a proportional basis. An explanation should accompany any monthly estimate which exceeds one-twelfth (1/12) of the total contract amount.
- (2) Monthly advancements will be made to contractors by the first of each month based on the monthly schedule of estimated requirements.

NOTE: As a matter of Commission policy, state funds will be used for the first month's advance; subsequent advances with federal funds will be considered as reimbursements on an estimated basis.

- (3) Contractors will submit quarterly actual expenditure reports within twenty-five (25) days following the end of each quarter.
- (4) Advancements for November, February, and May will be adjusted for variances between the previous quarters' estimated advancements and actual quarterly expenditures.
- (5) Within thirty (30) days following the end of the contract period, any unexpended advanced contract funds will be returned to the Commission.

e. Reimbursement - 100% Federal Funding
 100% State Funding
 Federal and State (Mixed) Funding

Payments will be made upon receipt of contractor's approved invoice and/or expenditure report.

f. Weekly Advance - 100% Federal Funding
 100% State Funding
 Federal and State (Mixed) Funding

- (1) Contractor will submit, in advance, a schedule of weekly cash requirements for the contract period.
- (2) The Commission will make weekly advance payments based on the schedule of weekly cash requirements.
- (3) Contractor will report actual expenditures on a monthly basis by the fifteenth (15th) of each month.
- (4) The first weekly advance following receipt of the monthly expenditure report would be adjusted for variance between amount advanced (four weekly advances) in the previous month and the actual monthly expenditures.

CONTRACT NUMBER

PAYMENT AND BUDGET PAGES

Page 14

CONTRACT TERM

CONTRACT

(Effective Date)

AMOUNT \$

(Termination Date)

For Fiscal Year 1985-86

PERSONNEL
(Name/Title)

SALARY (% TIME)

COMMISSION SHARE AND
TOTALS

Subtotal Personnel Costs \$

CONSULTANT COSTS

\$

EQUIPMENT (Itemize)

\$

SUPPLIES (Itemize)

\$

\$

CONTRACT NUMBER

PAYMENT AND BUDGET PAGES

Page 15

COMMISSION SHARE AND
TOTALS

TRAVEL

PATIENT CARE COSTS (Itemize into inpatient and outpatient categories) \$

ALTERATIONS AND RENOVATIONS TO SPACE (Itemize) \$

OTHER EXPENSES (Itemize) \$

TOTAL DIRECT COSTS

INDIRECT COSTS (Must not exceed 10% of budget request.) \$

TOTAL INDIRECT COSTS

TOTAL COMMISSION SHARE \$

CONTRACT NUMBER

PAYMENT AND BUDGET PAGES

Page 16

SOURCES OF PARTICIPATING FUNDS FOR CONTRACTOR'S SHARE OF PROJECT COSTS

- A. Contribution of Contractor or his/her affiliated institution \$ _____
 - B. Fees generated by project \$ _____
 - C. Grants from non-Commission Funds (identify) \$ _____
 - D. Participation by other agencies or organizations (identify) \$ _____
 - E. Other sources (explain) \$ _____
- TOTAL CONTRACTOR SHARE** \$ _____

CONTRACT NUMBER

PAYMENT AND BUDGET PAGES

Page 17

FUND SOURCE

COMMISSION SHARE

TOTAL PROJECT
COST

CONTRACT TITLE:

A. INSTITUTION/AFFILIATION ADDRESS

B. RESEARCHERS

Principal Investigator:

Co Investigator(s):

C. CONTRACT GOALS(S)

D. NOTICES, CORRESPONDENCE AND REPORTS**1. Program Reporting Requirements to the Commission****a. Progress Reports**

- (1) The Contractor shall submit a quarterly narrative, to be two to five single spaced pages. This narrative should be received by the Commission no later than April 30, 1986. The narrative should address the following questions:
 - i How far has the investigator progressed with implementation of the project?
 - ii What success has been achieved to date?
 - iii What difficulties have been encountered to date?
 - iv What is the projected outcome of the research at this date?
 - current goals (justify any alteration of the original goals)
 - (2) The Contractor shall submit a final report at the completion of the project. This report should include a summary of the progress and problems encountered as the research was implemented, a description of the accomplished outcome(s) and their significance, and any other information relevant to understanding the achievements of the contract. This report shall be ten to twenty single spaced pages.
- b. The Contractor shall submit to the Commission a quarterly expenditure report in a format approved by the Commission (Attachment A).
 - c. The Contractor shall submit to the Commission all statistical or other reports generated through the contracted research upon completion of the reports, but in no circumstances more than 90 days after the close of the contract period.
 - d. **Subcontract/Service Agreement:** The Contractor shall submit to the Commission the proposed subcontract or service agreement format to be used for the purchase of professional and outside services which must be approved by the Commission prior to negotiation of such subcontract or service agreement.
 - e. **Other Reports:** The Contractor shall submit such other reports as may be required by the Commission for the purpose of determining contract performance.
 - f. The Contractor shall agree to visits to the research facility by the Commission as required for the purpose of determining contract performance.

CONTRACT NUMBER

WORK STATEMENT

Page 20

2. Notices, Correspondence and Reports from the Contractor shall be sent to:

Linda Udall
Arizona Disease Control Research Commission
1740 W. Adams
Phoenix, Arizona 85007

3. Notices, Correspondence, Reports, and Payments from the Department shall be sent to:

E. QUALIFICATION OF RESEARCHERS

See Attachment B.

F. LICENSURE/CERTIFICATION REQUIREMENTS

1. Personnel/Facility

Maintain all applicable licenses pursuant to the Arizona Revised Statutes.

G. SPECIAL PROGRAM REQUIREMENTS

Approval by affiliated institution for the use of human or animal subjects.

(See Attachment D, if applicable.)

H. SERVICE NAME: Research

- I. SERVICE DEFINITION:** Research into the causes, epidemiology and diagnosis, the formulation of cures, the medically accepted treatment or prevention of diseases including new drug discovery and development.

K. SERVICE ACTIVITIES:

1. Conduct clinical, epidemiological, and/or behavioral research
2. Collect and analyze data
3. Review and summarize research findings
4. Author reports on conclusions of above

L. METHODOLOGIES for Service Delivery and Evaluation.

See Attachment C.

Purpose of Amendment: Clarification of portions of the special provisions and the Workstatement of this contract.

It is mutually agreed that the above-numbered contract is amended as follows:

- A. In reference to page seven of this contract, General Provision number 13, add the following:
 - f. The rights and remedies of the Department enumerated in this section shall be in addition to any other rights and remedies provided by or under this contract.
- B. In reference to page eleven of this contract Special Provision number 2 is deleted and in its place is amended to read:
 2. For the purposes of this contract General Provision 8a. is not applicable.
- C. In reference to page nineteen of this contract, the "Work Statement" D. is revised to read:
 - D. Notices, Correspondence and Reports
 1. Program Reporting Requirements to the Commission
 - a. Progress Reports
 - (1) The Contractor shall submit a report to the Commission by July 15, 1986. This report shall be at least five and no more than fifteen single spaced pages. The report shall consist of a summary of the progress and problems encountered as the research was implemented, a description of the accomplished outcome(s) and their significance, and any other information relevant to the understanding of the achievements of the contract.
 - b. The Contractor shall submit to the Commission two expenditure reports in a format approved by the Commission (Attachment A, "Quarterly Expenditure Report"). These reports should be received by the Commission on or before April 24 and July 15, 1986, respectively. One half of the contract amount will be advanced when the contract is executed by the Commission and the final payment shall be advanced on April 30, 1986.

All other paragraphs of Section D on page nineteen of this contract remain unchanged.

- D. In reference to page twenty of this contract, the Workstatement shall have the following addition to read:
- L. In addition to elements of the original proposal already outlined and/or attached to this workstatement, the entire original proposal submitted to the Commission by October 18, 1985 in response to the Request for Proposals (dated September 9, 1985), is incorporated by reference in this contract.

Name of Contractor	ARIZONA DISEASE CONTROL RESEARCH COMMISSION
Signature of Authorized Individual By:	Signature of Authorized Individual By:
Typed Name	Typed Name Linda M. Udall
Date	Date

CONTRACT NUMBER

QUARTERLY EXPENDITURE REPORT

Page

CONTRACT TERM

CONTRACT AMOUNT \$

(Effective Date)

For Fiscal Year 1985-86

(Termination Date)

PERSONNEL (Name/Title)

BASE SALARY (% TIME)

FRINGE

COMMISSION SHARE AND TOTALS

Subtotal Personnel Costs \$

CONSULTANT COSTS

\$

EQUIPMENT (Itemize)

\$

SUPPLIES (Itemize)

\$

\$

CONTRACT NUMBER

QUARTERLY EXPENDITURE REPORT

Page /

COMMISSION SHARE AND
TOTALS

PATIENT CARE COSTS (Itemize into inpatient and outpatient categories) \$

ALTERATIONS AND RENOVATIONS TO SPACE (Itemize) \$

OTHER EXPENSES (Itemize) \$

\$

TOTAL DIRECT COSTS

INDIRECT COSTS (Must not exceed 10% of budget request.) \$

TOTAL INDIRECT COSTS

\$

TOTAL COMMISSION SHARE \$

CONTRACT NUMBER

QUARTERLY EXPENDITURE REPORT

Page

SOURCES OF PARTICIPATING FUNDS FOR CONTRACTOR'S SHARE OF PROJECT COSTS

- A. Contribution of Contractor or his/her affiliated institution \$ _____
- B. Fees generated by project \$ _____
- C. Grants from non-Commission Funds (identify) \$ _____
- D. Participation by other agencies or organizations (identify) \$ _____
- E. Other sources (explain) \$ _____