

**FLORIDA CANCER CONTROL AND RESEARCH ADVISORY BOARD**

**FLORIDA CANCER CONTROL PLAN**

**A  
STATE OF FLORIDA  
COMMITMENT**

**October 20, 1985**

# Florida Cancer Control and Research Advisory Board

## Introduction

The Cancer Control and Research Act of 1979, Section 381.3712, Florida Statutes, created the Florida Cancer Control and Research Advisory Board (CCRAB) to advise the Secretary of the Department of Health and Rehabilitative Services (HRS) regarding cancer control and research in Florida.

The 25 members of the CCRAB include 20 representatives of organizations, agencies, and institutions with primary interests in cancer, three representatives of the general public, one state senator, and one member of the Florida House of Representatives. The Chairperson is appointed by the Governor from among the membership for a term of two years. All members serve voluntarily without compensation or reimbursement for travel or expenses.

Members chair or may serve on the Standing Committees which study specific issues relating to the function of the committee and recommend actions to the Board as a whole. The Standing Committees are organized functionally so that the following areas are established within entities: (1) Cancer plan evaluation: tumor registry, data retrieval systems, and epidemiology of cancer in the state and its relation to other areas. (2) Cancer prevention. (3) Cancer detection. (4) Cancer patient management: treatment, rehabilitation, terminal care, and other patient oriented activities. (5) Cancer education: lay and professional. (6) Unproven methods of cancer therapy: quackery and unorthodox therapies. (7) Investigator-initiated project research. In addition there is a Cancer Plan Committee made up of the Chairpersons of each functional committee and the Executive Committee.

Annually, a report is presented to provide information to the Governor and the Legislature regarding the activities of the Florida Cancer Control and Research Board which relate to cancer control activities in Florida.

## Florida Cancer Control and Research Advisory Board Programs

### I. Florida Cancer Data System

The Florida Cancer Data System (FCDS) was created by the Statewide Cancer Registry Law of 1978 (Section 381.3812, F.S.) which made cancer a reportable disease. Florida, with the highest crude cancer death rate in the nation, had, until this legislation, no reliable mechanism to assess the significance of this fact.

The FCDS is a fully computerized central state cancer registry, totally funded by the State of Florida. The data items collected by the individual hospitals and submitted to the system are compatible with national standards set by the American College of Surgeons, the Surveillance, Epidemiology and End Results reporting program (SEER), and the Centralized Cancer Patient Data System, the latter two which are funded by the National Cancer Institute for the collection of cancer data.

The objectives of FCDS are:

1. to determine the regional and statewide incidence and prevalence of cancer;
2. to improve research and provide more accurate statistics;
3. to document high-risk populations and statewide environmental carcinogenic patterns;
4. to identify trends in the disease;
5. to study baseline data for qualitative analysis of cancer mortality statistics;
6. to provide information for public education;
7. to compare effectiveness of various treatment modalities.

Periodic reports regarding certain characteristics of reported cancers such as age, race, sex, county of treatment, site of cancer, date of diagnosis and county of residence are submitted to HRS. Data base information is available to researchers through the authorized departments of the University of Florida, the University of Miami and the University of South Florida.

### II. Breast Cancer Treatment Options Information

In response to Chapter 84-222, Laws of Florida, regarding Breast Cancer Treatment options a brochure, "Breast Lumps", a guide to understanding breast problems and breast surgery, was made available to the physicians of the State of Florida and a plan implemented to distribute the brochure to inform citizen groups, associations and voluntary organizations about the early detection and treatment of breast cancer.

## Florida Cancer Control Plan

The goal of the Director of the National Cancer Institute, to reduce by one half the annual deaths from cancer in the United States by the year 2000, is a formidable challenge for the Florida Cancer Control and Research Advisory Board, the citizens of Florida and their government. The Florida Cancer Control Plan has been developed to meet this challenge.

### I Problems

#### A. Florida has the greatest cancer problem of all 50 states.

1. 1981- Fla.	46,902 new cases	481 per 100,000 persons	
1981- U.S.(S.E.E.R.)	new cases	325 per 100,000 persons	(1)
2. 1981- Fla.	24,200 deaths	248 per 100,000 persons	
1981- U.S.(S.E.E.R.)	422,094 deaths	167 per 100,000 persons	(2),(3)

#### B. Florida's cancer problem is related to its elderly population.

1. 1981- Florida	about 2/3 of all cancer cases are 65 yrs old or older		
Nationally	about 1/2 of all cancer cases are 65 yrs old or older		(7)
2. 1981- Fla.	incidence rate falls from 481 to 314 when age adjusted to the U.S.(S.E.E.R.) incidence rate of 325		(1)
3. 1980- The Elderly in Florida	comprise 17.3% of the population		
The Elderly in other states	comprise less 13% of the population		(8),(10)

#### C. Florida's cancer problem will grow rapidly by the year 2000.

1. 1980- Florida	10,000,000 population	17.3% elderly	
2000- Florida	15,000,000 population(est.)	19.4% elderly(est.)	(8)
2. 1980- Fla. Elderly pop.	1,687,573	26,942 elderly cancers	
2000- Fla. Elderly pop.	2,917,870(est.)	48,802 elderly cancers(est.)	(8)

#### D. Cancer incidence and mortality are higher in economically disadvantaged.

1. Incidence of cancer in males	White 371 per 100,000 persons		
	Black 454 per 100,000 persons		(4)
2. 1981 U.S.(S.E.E.R.) cancer death rate	White 162 per 100,000 persons		
	Black 216 per 100,000 persons		(9)
3. 1976 -1981 cure rate from cancer	White 50%		
	Black 38%		(5)

#### E. Cancer is more advanced in economically disadvantaged.

1. 1967-1973 Localized (curable) cancer at time of treatment	White male 37%	White female 42%	
	Black male 28%	Black female 31%	(6)

#### F. Cost of treatment and management is greater for advanced cancer.

The opportunity for cure is three to four times greater for early localized cancer than for advanced cancer. Thus, the treatment of early cancer is many times more cost-effective in saving both lives and money.

## II Plan

Florida must take measures to change the pattern of cancer through

1. Programs of prevention
2. Programs of early detection

directed at the major cancer sites

1. Lung
2. Colo-rectal
3. Breast
4. Uterus- Cervix & Body
5. Ovary
6. Prostate
7. Skin

consisting of

1. Prevention Education
2. Prevention Intervention Strategies
3. Identification and intervention procedures aimed at early diagnosis in the high risk cancer population
4. Support for early diagnosis in the economically disadvantaged population and the elderly

In addition to saving thousands of lives, changing the pattern of cancer in Florida is an effective method of health care cost containment.

### III Plan Funding

- A. Smoking was the cause of 17,200 deaths in Florida in 1981:  
(15.8% of all deaths and almost 25% of cancer deaths)
- B. Direct economic costs were considerable, 843 million dollars
- C. Indirect costs were 160% of direct costs, thus  
Total Cost of Smoking in Florida was 2.19 billion dollars in 1981
- D. In 1981, 1,323,503,960 packs of cigarettes were sold in Florida  
which generated 21c per pack revenue in contrast to  
direct health care costs of 64c per pack and  
total costs of \$1.66 per pack
- E. A one cent per pack additional tax on cigarettes will  
generate sufficient funds needed to impact on the cancer  
control problems of Florida.

#### IV Plan Implementation

The Florida Cancer Control and Research Act of 1979 created the Florida Cancer Control and Research Advisory Board(Fla.CCRAB) and the Florida Cancer Control and Research Fund(FCCR Fund). To date, there have been no funds appropriated or otherwise obtained for the FCCR Fund. The deposit of a one cent per pack additional tax on cigarettes in this fund would permit the Fla.CCRAB and the Florida Department of Health and Rehabilitative Services to implement this plan to alleviate the impact of Florida's cancer problems. Projects to carry out the plan have been submitted to the Fla.CCRAB and reviewed but not evaluated and approved as yet for implementation. If sufficient funds become available, these projects and others that may be submitted to the Fla. CCRAB will be submitted to qualified reviewers for peer-review, evaluation and prioritization. Those meeting the highest standards will be approved by the Fla.CCRAB for recommendation to the Florida Department of Health and Rehabilitative Services for implementation.

Projects Submitted for Funding  
to the Florida Cancer Control and Research Advisory Board

I. Administration (A-1)		337,608
A. Staff Salaries	224,650	
B. Travel and Expenses	93,610	
C. Operating Capital Outlay	19,348	
II. Florida Cancer Plan (A-2)		250,000
III. Florida Cancer Data System (A-3)		1,208,000
A. Replace Present HRS Budget		640,000
1. Central Operation	400,000	
2. Hospital Reimbursement	240,000	
B. New Expenditures		568,000
1. V.A & Military Hosps. Collection	150,000	
2. Quality Control	175,000	
3. Data Analyses and Reports	200,000	
4. Follow-up; ACoS Registries	43,000	
IV. Epidemiologic & Demographic Studies		
A. A Case Control Study of Lung Cancer in Northern Florida (A-4)		180,000
B. Radium Groundwater Contamination & the Risk of Leukemia (A-5)		132,666
C. Hazardous Waste Exposure and Cancer (A-6)		150,000
V. Intervention Projects		
A. Primary Prevention		
1. Smoking Intervention Programs and Comparative Evaluative Analyses (A-7)		100,000
2. Cessation of Smoking in Adults (A-8)		80,400
3. Smoking Cessation Among Nurses (A-9)		40,000
4. Smoking and Nutrition Intervention (A-10)		19,200
5. Smoking Cessation Program for Pregnant Women (A-11)		70,000
6. Cis-Retinoic Acid Prevention of Cancer (A-12)		86,400
7. A Study of Dysplastic Nevi Syndrome and Skin Cancer (A-13)		84,000
8. Prevention of Colon Cancer in Patients at High Risk (A-14)		140,000
9. Role of Dietary Intervention in Reduction of Colon Carcinoma in Patients at High Risk (A-15)		200,000
B. Secondary Prevention		
1. Program for Early Detection of Colon Cancer Among the Population at High Risk (A-16)		500,000
2. U. of S. Fla. Program for Multiphasic Cancer Detection in Women (A-17)		336,000
3. Breast Cancer Detection Program (A-18)		775,000
4. Targetted Cervical Cancer Control in Florida (A-19)		500,000
5. Colorectal Screening for Indigent Patients (A-20)		442,000



C. Health Care Delivery Systems

1. Cancer Care Network of Florida (A-21)		750,000
Core Grant	250,000	
Programs	500,000	
2. Childhood Cancer Control (A-22)		400,000
3. Medical Care Delivery as a Risk Factor For Invasive Cervical Cancer (A-23)		80,000
4. Health Care Utilization, Risk Factors & Disease Among Hispanics in Florida (A-24)		70,500
5. Clinical And Investigative Bone Marrow Transplantation Program For Florida (A-25)		680,000
6. Technology Transfer (A-26)		250,000

VI. Education

A. Evaluative Comparisons of Special Programs for the Deterrence and Delay of Smoking Among Youth (A-27)		240,000
B. Reducing the Delay in Seeking Medical Care (A-28)		175,000

VII. Research Fund

A. Basic Research Fund (A-29)		2,000,000
1. Biochemistry of Mammary Neoplasia (A-30)	100,000	
2. Rodent Tumor Distribution in S.W. Fla. (A-31)	83,425	
3. Prostatic Cancer (A-32)	135,000	
4. Reversion of Malignant Cells Phenotype (A-33)	110,000	
5. New Immunotherapeutic Strategies for the Management of Cancer (A-34)	500,000	
B. Clinical Research Fund (A-35)		2,000,000
C. Epidemiological Research Fund (A-36)		1,000,000
1. Developing Strategies For Cancer Control Among the Elderly (A-37)	20,000	
2. Investigation of Cancers That Occur Excessively Among Blacks (A-38)	350,000	
3. Study of Cancer and Immunodeficiencies Among Drug Users (A-39)	70,000	
4. Case Control Study of Cervix Cancer in Latin Women (A-40)	280,000	
5. Cigarette Smoking and the Risk of Breast Cancer (A-41)	102,833	

Total Budget

13,276,774

## References for Florida Cancer Control Plan

- (1) Page 11 Cancer In Florida, Statewide Incidence Report  
Department of Health and Rehabilitative Services  
State of Florida
- (2) Page iii Cancer in Florida, Statewide Incidence Report  
Department of Health and Rehabilitative Services  
State of Florida
- (3) Page 3 1985 Cancer Facts and Figures  
American Cancer Society
- (4) Page 5 Cancer Facts and Figures for Minority Americans  
1983  
American Cancer Society
- (5) Page 2 Editorial by LaSalle D. Leffall, Jr, M.D.  
Oncology Times September 1985,
- (6) Page 13 1985 Cancer Facts and Figures  
American Cancer Society
- (7) Page 7 Cancer Data and Planning Activities in Florida  
Papanicalaou Comprehensive Cancer Center  
Miami, Florida July 1985
- (8) Page 11 Cancer Data and Planning Activities in Florida  
Papanicalaou Comprehensive Cancer Center  
Miami, Florida July 1985
- (9) Cancer Incidence and Mortality in United States  
S.E.E.R. 1973-1981  
U.S. Dept. of Health and Human Services 1984
- (10) Bureau of Census

APPENDIX

FLORIDA CANCER CONTROL PLAN

I. Administration

A. Staff

1. Medical Executive Director	82,741	
2. Medical Health Care Prog. Mngr.	41,299	
3. Sr. Hum. Ser. Prog. Mngr. (2)	65,016	
4. Senior Secretary	18,694	
5. Secretary Specialist	16,900	
Total Salaries & Benefits		224,650

B. Expenses

1. Travel members to meetings	30,000	
2. Maximum travel 4 professionals	26,176	
3. Standard expenses 4 professionals	18,668	
4. Standard expenses 2 secretaries	8,266	
5. Printing and Mailing	10,500	
Total Expenses		93,610

C. Operating Capital Outlay

1. Computer Equipment	10,000	
2. Xerox Memory Writer (2)	3,792	
3. Furniture, office	5,556	
Total Operating Capital Outlay		19,348

Total Administrative Costs 337,608

II.

Florida Cancer Plan

Clyde B. McCoy, Ph.D.  
Edward J. Trapido, Sc. D.  
Papanicolaou Comprehensive Cancer Center

The Cancer Plan for the State of Florida is a comprehensive program for targeting, tailoring and coordinating cancer prevention, detection, diagnosis and treatment activities to the needs of the population in general, but especially to the unique and/or higher risk subgroups that are represented within the State. The plan is fundamentally based on information about the demographic characteristics of the state's population, projections of growth, immigration and migration, epidemiologic research on the distribution of cancer within the population and the availability of both preventive and treatment services. Although a multi-organizational and multidisciplinary team has drafted the Plan, the major inputs have been provided by the Papanicolaou Comprehensive Cancer Center and the Division of Health and Rehabilitative Services for the State of Florida.

This long-range, comprehensive Plan projects the need for prevention, diagnostic, detection and treatment services through the year 2000. It is based upon a model which posits that improved availability, accessibility and utilization of cancer control services will lead to earlier detection and treatment which translates to reduced cancer incidence and mortality by the year 2000. The Plan itself will be structured to facilitate the generation of specific hypotheses and seeks to develop and apply appropriate methodologies needed for both the implementation and evaluation of cancer control studies. Specifically, this Plan will:

1. Identify concentrations of high risk populations in Florida in terms of geographic locations within the State, with emphasis on selected urban areas and on demographic characteristics, places of residence and socio-economic status.
2. Define high risk groups and areas where specific types of cancers are in excess of normal expectations in terms of specific types of cancers as defined by site and morphology, socio-economic status, behavior and life style.
3. Profile the scope, availability, accessibility and utilization of cancer control services for selected high risk populations in terms of screening and referral, diagnostic and treatment services and hospice or terminal care services.
4. Objectively compare the profile of existing cancer control services to specific high risk populations.
5. Seek to improve cancer control services for the selected study populations by means of:
  - a. Analysis of relationships between existing cancer control services and health care needs in selected geographic areas, and
  - b. Personal contact and communication by project team with key service providers, community and religious organizations, and consumers of cancer control services.
6. Development of intervention strategies which will improve consumers' utilization of and benefits from existing cancer control services.
7. Develop methodologies to assess the impact of intervention strategies upon early diagnosis, patient care and case management.

Two year project.

Annual cost \$ 250,000.00

III.

Florida Cancer Data System

A. Data Collection Central Operation: The current operating budget of the Florida Cancer Data System (FCDS), \$400,000.00, provides for the central operating costs related to processing the statewide cancer data. These costs are associated with processing, purifying, and storing approximately 70,000 cases annually. The current operating contract does not provide the costs necessary for collection of cases from sources not licensed under Chapter 395, (e.g. Veterans Administration and Military Hospitals), quality control of the data beyond the computerized edit checking procedures, reporting the data beyond raw data tapes, or collection of follow-up data.

B. Veterans Administration and Military Hospitals: The number of incident cases being missed by not collecting data from the V.A. and Military Hospitals is estimated to be as much as 10% of the state total. A pilot project at the V.A.H. in Miami has shown that ascertainment of the V.A.H. cases can not be done retrospectively. Full-time FCDS employees must be placed in the V.A. hospitals to actively gather these data in a timely fashion. The annual operating budget which would allow FCDS to collect data from V.A. and Military hospitals would be \$150,000.00.

C. Quality Control: The FCDS must implement a quality control program which goes beyond merely performing computerized inter- and intra-item edit checks. This quality control program would include a thorough review of hospital case identification sources to insure against "missed cases", reabstraction of previously submitted records to ascertain data quality, and periodic abstracting studies to ascertain abstractor accuracy. The quality control program would require an annual budget of \$175,000.00.

D. Data Analysis and Reports: In the past FCDS has been able to produce reports on an ad hoc basis only. These reports have been minimal and have not begun to fulfill the needs of the health professionals in Florida. The major responsibility of the Data Analysis and Reports section of the FCDS would be to produce comprehensive annual analyses of the statewide data in a county by county tabulat form. These monographs would allow health professionals to extract data from FCDS quickly and easily without having to make special requests for reports to be compiled from the raw data. Also, hospitals require many types of unique reports for which statewide incidence reports are not sufficient. The Data Analyses and Reports section of FCDS would provide hospitals with the unique analyses and reports required, thus providing many hospitals with the ability for the first time to actively understand their part in the state's care and treatment of the cancer patient. This would require an annual operating budget of \$200,000.00.

E. Follow-up: In order to follow every case of cancer in the state from the central registry, the estimated caseload in the fifth year would be 179,000 at an annual cost of approximately \$ 839,000, or approximately \$4,600 per 1000 cases. This could be done for an annual cost of over \$235,000 for the first year, \$410,000 the second year, etc. An alternative to the active following of every case in the state is passively to follow cases through hospitals that have an American College of Surgeons approved program. These hospitals currently care for approximately 30 percent of the cancer patients in Florida and it is expected that within the next two years will care for approximately 60 percent of the cancer patients in Florida. Passively following the cases through ACoS hospitals could be done for approximately \$400 per 1000 cases for an annual operating budget of \$6,00 for the first year, \$10,000 for the second year, etc., stabilizing at \$43,00 per year.

Annual program	Operations Cost	400,000.00
	Hosp. Reimbursement	240,000.00
	V.A. & Military Hosps.	150,000.00
	Quality Control	175,000.00
	Data Analyses & Reports	200,000.00
	Follow-up	43,000.00
	Total	\$1,208,000.00

IV. A. A Case Control Study of Lung Cancer In Northern Florida

Clyde B. McCoy, Ph.D.  
Edward J. Trapido, Sc. D.  
Papanicolaou Comprehensive Cancer Center

Sparked by reports of high mortality from lung cancer in Northern Florida, case control studies have been performed that suggest that neither occupation nor smoking fully accounts for the excess risk associated with living in that area. Recent data from the Florida Cancer Data System further documents that the excess risk applies to incidence as well as mortality, suggesting that lack of adequate or effective health care does not account for the excess. However, since the incidence data suggests that the excess risk was not evident among blacks, we propose to perform a case control study of incident cases that will focus on black-white differences in risk factors. Besides smoking and occupation, we will focus on residential history, as well as exposure to environmental hazards.

Five year study.

Annual cost \$ 180,000.00

#### IV. B. Radium Groundwater Contamination and the Risk of Leukemia

G.H. Lyman, M.D., M.P.H., College of Medicine  
H.G. Stockwell, Sc.D., College of Public Health  
C.G. Lyman, R.N., College of Medicine  
University of South Florida

In cooperation with the Florida Department of Health and Rehabilitative Services (FDHRS), we have recently reported evidence of considerable radium groundwater contamination in Southwest Florida. Utilizing data available from the Florida Cancer Data System, we have demonstrated a strong association between the geographic clustering of incident leukemia cases and groundwater contamination. We have also observed similar associations between incident leukemia cases and drinking water contamination in this region. This summary represents a proposal to conduct a case control study to assess the possible causal relationship between radium contamination and leukemia.

New cases of leukemia diagnosed at participating medical centers in a five county area will be reported to the study center. These counties would include Sarasota, Lee, Charlotte, Hardee and Manatee, representing those counties with radium contamination of more than 20% of groundwater samples taken. Patients will be identified at the time of histologic diagnosis at participating hospitals. All cases of leukemia will be identified and subclassified according to the French American British (FAB) system. Study personnel will contact the patient's physician to request permission to interview the patient. Age, race, and sex matched control subjects would be simultaneously identified from patients hospitalized with nonmalignant disorders. After obtaining physician approval, each case and control subject would be contacted for possible study entry. Trained study personnel would interview consenting individuals in their home obtaining a full medical, family, occupational and social history. Histologic material will be reviewed for confirmation of diagnosis and subtyping. Likewise, samples of tapwater and both home and store-purchased food-stuff will be obtained. Samples will be delivered to the study laboratory for assay of a battery of agents including radium, radon and other radionuclides as well as organic solvents and a variety of other potential carcinogens. It is anticipated that the FDHRS will cooperate with part of the testing program to minimize duplication of resources.

While leukemia represents less than 10% of all malignancies in the state, the short latency period and clinical behavior of the disease may permit measurement of effects which would be difficult to assess in other disease categories similarly affected. While radium groundwater contamination has been demonstrated in this area, many potential carcinogens have not been assessed in any systematic fashion. The results of these investigations should improve our understanding of the general problem of environmental carcinogenesis. The results of preliminary studies demonstrating an association between leukemia and radium water contamination need to be investigated further before major public health intervention can be planned.

Three year project

Annual cost \$ 132,666



IV. C.

Hazardous Waste Exposure and Cancer

Dale C. Chitwood, Ph.D.  
Robert S. Levine, M.D.  
Edward J. Trapido, Sc.D.  
Clyde B. McCoy, Ph.D.

Papanicolaou Comprehensive Cancer Center

Several hazardous waste sites have been identified in Florida. Groundwater resources of the state are particularly vulnerable to contamination by uncontrolled hazardous wastes, because much of the state is covered by highly permeable sands and soils which overly limestone. Contamination from disposal sites and other sources quickly penetrates these formations, enters the underground water table and becomes a potential health threat to Floridians. However, no thorough investigation of the effect of exposure to hazardous waste has been conducted in Florida.

This project will review data about each hazardous waste site in the state and select specific site(s) which the data suggest has the highest potential for producing adverse health consequences among the residents of the area where the site is located. A retrospective cohort study of exposed and non-exposed residents will be conducted to assess the health effects of exposure to hazardous wastes.

Five year project.

Annual cost \$ 150,000.00

Smoking Intervention Programs --  
and Comparative Evaluative AnalysesAmerican Lung Association of Florida  
Univ. of Florida., Univ. of South Florida., Univ. of Miami

Stephen F. Willcox, Investigator

Given the strong evidence linking smoking to cancer and recognizing that no single measure that is presently known would have a greater impact on the number of deaths attributable to cancer, it is most important that smoking intervention programs be implemented within the state in order to provide support systems for people in their efforts to quit smoking. The American Lung Association of Florida has three distinct programs for implementation within the workplace. Selected workplaces employing significant numbers of persons will be recruited to institute the lung association smoking programs. These programs will be monitored and evaluated for their longterm effects upon the behavior of people to quit smoking. In addition to measuring the outcome of smoking cessation, the evaluation will also include process evaluation to determine the components of the program which are most successful and which behavior patterns are most important in changing smokers into non-smokers.

The American Lung Association of Florida has three differing interventions that should be effective in the workplace.

1. A clinical program providing in depth counseling which is entitled "Freedom from Smoking".
2. A 20 day self-help program which is tailored for people who need materials for assistance but do not need the clinical interaction to assist their smoking cessation.
3. A video program entitled "In Control" which permits individuals to rent or buy the video tape with assisting materials that allows the individuals to proceed at their own pace with minimal assistance from other individuals in a counseling program.

Although these programs have been tested for effectiveness with the general public, they have not received the type of longterm evaluation that would allow conclusive evidence as to which was most effective in the deterrance of smoking for long periods of time after completion of the programs in the workplace environment. Ideally, employees within workplaces who would volunteer for the smoking program would be randomized to one of the intervention strategies to determine which of the programs was most effective in the long term reduction of smoking. The program participants would be followed up on an individual basis at periodic scheduled times after completion of the program over a five year period. The initial evaluation would occur immediately after the program and six months later after which time there would be an annual assessment of the individuals behavior relative to smoking and other possible compensatory behavior such as dieting, stress and other factors which are possibly important in smoking programs. The implementation of the program would be assisted throughout the state by the American Lung Association of Florida. The American Lung Association would work with the three medical schools in Florida; the University of Miami, the University of Florida and the University of South Florida, in designing and carrying out the long term evaluation of the program's effectiveness.

Five year program

Annual cost \$ 100,000.00

Duane McBride, Ph.D.  
University of Miami

It is the basic purpose of this project, using a matched pairs design, to evaluate and modify, based on the evaluation, a hospital based Stop Smoking Program. The program to be evaluated is a service of Hialeah Hospital in Hialeah, Florida. Hialeah Hospital is an institution owned and operated by the Seventh-Day Adventists and the hospital's Stop Smoking Program is based on the five day Stop Smoking Plan developed by the Seventh-Day Adventist Church.

The specific aims of this project are to:

1. Evaluate the success of the Stop Smoking Program in recruiting program participants reflective of the population characteristics and smoking patterns of the community served by the hospital.
2. Conduct a follow-up study of the program entrants and a matched pairs controlled group to determine retention rates (in the Stop Smoking Program) and smoking patterns 3, 6, and 12 months after program exit or completion in the program group and 3, 6, and 12 months after baseline data collection in the control group. There will be a particular focus on specifying changes or lack of changes by population characteristics.
3. Based on the comparison of the program population to the market area population needs and the determination of retention rates and changes in smoking behavior for specific populations, recommendations will be ~~provided to the program for better meeting market area needs and to~~ improve retention and smoking cessation rates particularly for populations with limited retention and success in the existing program.
4. Assist the Stop Smoking Program in implementing recruiting and program modifications.
5. Evaluate new recruitment procedures and modified program retention and outcome for specific populations per objectives 1 and 2.

Five year project

Annual cost \$ 80,400.00

Dale C. Chitwood, Ph.D.  
University of Miami

Unlike physicians, the prevalence of smoking among nurses has not dropped in the last decade. Estimates suggest that about 40% of nurses still smoke, with an even greater percentage of younger nurses still smoking. We propose to develop a targeted intervention program that would provide education on cessation of smoking, counseling, stress reduction and weight maintenance. The latter two factors being important in maintaining abstinence from smoking. Nurses would be selected from two hospitals, and one hospital would be designated as receiving this year one intervention program. Baseline interviews would be conducted in both groups, as would periodic follow-up interviews (for a total follow-up of five years). The effectiveness of short and long term smoking cessation would be assessed in each group (and compared), as well as determining the cost/benefit of the intervention program.

Five year project.

Annual cost \$ 40,000.00

George Christakis, M.D.  
Terence A. Gerace, Ph.D.  
University of Miami

The Multiple Risk Factor Intervention Trial (MRFIT) methods and experiences in Miami have provided a strong base upon which it is proposed to develop an efficient model to reduce the risk of smoking and nutrition related cancers. The proposed research project will integrate appropriate elements of the MRFIT programs into a cancer risk factor reduction protocol, administer the program to a high risk sample of 200 Cuban and non-Cuban men and compare short and long term results with 150 control subjects drawn from the same risk pool. It is hypothesized that a smoking cessation and nutrition intervention program can significantly reduce cancer risk among Cuban and non-Cuban males.

Five year project.

Annual cost \$ 19,200.00

V. A. 5.

A Smoking Cessation Program for Pregnant Women

Division of Cancer Control  
Papanicolaou Comprehensive Cancer Center

An increasing amount of evidence suggests that smoking during pregnancy results in low birth weight babies, an increased incidence of prematurity, and increased risk of neonatal death. In addition, although many long term smokers appear to be quite motivated during pregnancy to quit smoking, a return to the habit is not uncommon.

We propose to perform an intervention program in a prenatal clinic, classifying women as never having smoked, smoked until the beginning of pregnancy or current smokers. The current smokers will be randomized to two groups, one receiving normal medical and prenatal care (which usually includes some anti-smoking advice, and one receiving a smoking cessation program which will continue for a year beyond delivery. Outcomes in all groups will be measured for two years following delivery, and will focus on infant's health, as well as on a comparison of the prevalence of maternal smoking, assessed at monthly intervals. For the smokers, major attention will be given to the effects of the number of months during pregnancy that a woman smoked.

Three year program

Annual Cost \$ 70,000.00

V. A. 6. Cis-Retinoic Acid Prevention of Cancer

David Schapira, M.D.  
Papanicolaou Comprehensive Cancer Center

The primary objective is to estimate the effectiveness of 13-cis retinoic acid in preventing the progression of moderate and/or marked atypia of the bronchial epithelium toward carcinoma-in-situ. Persons with at least 20 pack years of cigarette smoking and with moderate or marked atypia will be randomized to receive 13-cis retinoic acid or a placebo. Neither the participants nor the pathologist evaluators will be aware of the treatment arm to which randomization has occurred. Dosage for those receiving 13-cis retinoic acid, however will be adjusted to minimize side effects. Also, participants who progress from moderate to marked atypia while on placebo will be crossed over to 13-cis retinoic acid. All participants will be carefully monitored as to sputum cytology for a minimum of two years. Progression to carcinoma-in-situ will cause the participants to be removed from the study.

Five year project

Annual cost \$ 86,400.00

V. A. 7. A Study of Dysplastic Nevi Syndrome and Skin Cancer

Edward J. Trapido, Sc.D.  
Larry Garland, M.D.  
University of Miami

The proposed study will identify individuals who have dysplastic nevi syndrome, a pre-malignant lesion that is associated with a dramatically elevated risk of developing skin cancer. Since such lesions may aggregate in families, all family members of the index case will also be identified. For half of the families, we propose to provide examination and instruction on how to recognize these lesions, using the Pigmented Tumor Clinic at the University of Miami School of Medicine for those who live in South Florida, and educational materials and suggestions for medical referrals to individuals who do not live locally. The other families will receive standard medical care. Over a five year period, we will monitor the occurrence of skin cancer diagnosed in both groups to determine whether the intervention was effective.

Five year project

Annual cost \$ 84,000.00



V. A. 8. Prevention of Colon Cancer in Patients at High-Risk

Dean McCarley, M.D.  
Charles Hitchcock, Ph.D., M.D.  
Charles King, M.D.  
Roy S. Weiner, M.D.  
University of Florida

Dietary impact on the development of colon cancer has received considerable attention among clinicians, nutritionists and epidemiologists over the years. The biological bridge between diet and carcinogenesis may well be the colonic bacterial flora and its role in tumorigenesis or tumor production. A cellular correlate of tumor promotion may be reflected in the kinetics of colonic mucosa both proximal to and distal to colonic polyps. The pilot study undertaken at the University of Florida will measure the effect of colonic bacterial flora on the mucosal cell kinetics and the recurrence of polyps in patients who have undergone polypectomy. An attempt will be made to alter the bacterial flora to favor Bifidus through the ingestion of a specially cultured milk product on a long term basis. Support is requested for the pilot study which involves measurement of colonic flora and pH as well as kinetic profile of colonic mucosal cells by flow cytometry and surveillance for recurrent polyps by colonoscopy.

Three year project.

Annual cost \$ 140,000.00

V. A. 9.

The Role of Dietary Intervention in Reduction  
of Colon Carcinoma in Patients at High Risk

Roy S. Weiner, M.D.

Dean McCarley, M.D.

University of Florida

Based on the results of the ongoing pilot study which measures the effect of altering the colonic mucosa on colonic cell kinetics and recurrence of polyps, we would propose a large scale Phase III dietary intervention study in patients at high risk of colon cancer. Since colon cancer is a leading cause of cancer/death in both men and women, and since risk categories are definable in terms of family history and the presence of colonic polyps or other colonic diseases, such an intervention study could result in the saving of significant numbers of lives. Benefit to the entire study population irrespective of the randomization to the control or the intervention arm would accrue by virtue of the fact that these patients would be under close surveillance and should colonic cancer develop, early detection would be much more likely. The proposed intervention would consist of the addition of Bifidis containing milk product to the diet of patients at high risk on a daily basis with the verification that the colonic flora has shifted from coliform organisms to the acid forming Bifidis. This study would involve 1,000 patients at high risk with physician contact for surveillance at three month intervals.

Ten year project

Annual cost \$ 200,000.00



V. B. 2.

The University of South Florida Program  
For Multiphasic Cancer Detection in Women

Dennis Cavanagh, M.D.  
Philip A. Townsend, M.D.  
Gary H. Lyman, M.D.  
University of South Florida

We propose the establishment of an early diagnostic screening program for cancers in women of more than 40 years. A pilot study will be established to screen a population of 5,000 women. From such an initial study, we expect to gain the necessary experience and a data base on which to build a service that can be offered with benefit to all women over 40 years of age in Florida. The cancers included in this program are breast, colo-rectal, ovary, and uterus and our aim is the early detection of those cancers responsible for almost half the cancer deaths in women and for those women who do not smoke cigarettes, this figure is more than 60%. Following the pilot study, it is hoped that 5,000 women can be screened annually to allow the accumulation of sufficient data to answer comprehensively the effectiveness and value of this multiphasic cancer screening program. At least five years should be allowed to achieve such data accumulation and analysis.

Five year program

Annual cost \$ 336,000.00

## Breast Cancer Detection Program

Roy S. Weiner, M.D.  
 Jeffrey P. Krischer, Ph.D.  
 University of Florida

An estimated one out of every eleven women will develop breast cancer in her lifetime. The incidence of about 6,000 cases per year in the State of Florida makes breast cancer virtually epidemic. Breast cancer is a risk for all women; the risk is significantly increased after age 50 and if there is a family history of the disease. There is considerable evidence from past studies that early detection of breast cancer is associated with a more favorable prognosis. Screening, which involves breast self examination, physical examination and mammography has been shown to improve the chance of early detection and thus be effective in reducing breast cancer mortality.

## Recommendations:

1. The reported low incidence of the use of established breast cancer screening modalities (monthly BSE and mammography) among a population known to be at high risk provides a strong argument for continued surveillance and attempts to promote increased screening, consistent with recommended screening practices.
2. The presentation of advanced stage breast cancers by 13% of the population suggests a need for increased public awareness and education for all women in the State to promote earlier detection.
3. An educational program should be directed to primary care physicians to promote screening practices consistent with good medical care.
4. A statewide program for screening and early detection should be implemented, along with a program to monitor and evaluate its impact.
5. The methodology utilized in this study recommends a continuation of these efforts to identify, contact and educate relatives of breast cancer patients who are at increased risk to promote screening for earlier breast cancer detection.

Program to Identify High Risk by Family History	\$350,000.00
Mammography for Indigent High Risk Women	\$200,000.00
Women Over 50 Education program	\$225,000.00

Annual program.

Annual cost \$ 775,000.00

V. B. 4. Targetted Cervical Cancer Control in Florida  
A Plan for Reduction in Avoidable Mortality from Cancer

Clyde B. McCoy, Ph.D.  
Robert S. Levine, M.D.  
Papanicolaou Comprehensive Cancer Center

A population based intervention program using PAP smears will be implimented for the detection of cervical disease. Factors relating utilization of the program to changes in the incidence of invasive and in-situ cervical cancer will be evaluated. An adaptation of the case-control methodology will be used to distinguish utilization factors from etiologic factors, and for public health purposes, will allow estimations of the population-based relative and attributable risks associated with the intervention. The program will be conducted in Palm Beach County, Florida, which, on the basis of demographic and epidemiologic characteristics, suggests that it is comparabe to other U.S. communities in need of enhancement of cervical cancer screening programs.

Five year program

Annual cost \$ 500,000.00

## Colorectal Screening for Indigent Patients

Daniel Seckinger, M.D.  
Margaret S. Skinner, M.D.  
Cedars Medical Center

The current prevalence of colorectal cancer in people over 50 is three per one thousand. The specificity of the occult bleeding screen for colorectal cancer approaches 99%. This means that of the people who have cancer of the colon, approximately 99% of them will at some time or another exhibit a positive occult blood screening test. In several of the large series which have been undertaken so far, colorectal cancer has been found in approximately six percent of the people undergoing the test. The encouraging data is that the sixty to sixty-eight percent of the patients whose cancers are first investigated because of a positive occult blood test will have very early lesions. In the same study, of patients whose colorectal cancers were discovered by other detection means, only 39% were of the very early stage. An additional 13% to 15% of the patients in screening studies are discovered to have polyps. Polyps in certain instances are pre-malignant conditions which if discovered before the stage at which true invading cancer occurs can be rather simply removed through an endoscopic or similar non-surgical procedure. Comparative cost of treatment of colorectal carcinoma with and without screening for occult blood is outlined below.

## A. Data

Total Dade County Population	1,700,000
Population at or below poverty level (13%)	221,000
Risk Group (over 50) at or below poverty level (40%)	88,400
Positive screen rate (6.0%)	5,304
Cancer rate in positive screens (6.6%)	350
Polyp rate in positive screens (15%)	796

## B. Cost of Screening and Treatment

Treatment of Polyps (796 x \$1,500)	\$1,194,000
Early colorectal cancer $2/3 \times 350 = 223$ pts @ \$5,500	\$1,165,000
Advanced colorectal cancer $1/3 \times 350 = 117$ pts @ \$35,000	\$4,095,000
Cost of follow-up of positive screens not due to colorectal cancer or polyps 4,158 pts @ \$1,000	\$4,158,000
Cost of screen (occult blood), include reagents, labor, data processing and records	\$442,000
Cancer Deaths 117 (est.)	TOTAL COST
	\$11,054,000

## C. Cost of Treatment without Occult Blood Screening

Patients with advanced colorectal cancer (55%) $0.45 \times 350 = 157$ @ \$35,000	\$6,755,000
Patients with early colorectal cancer (45%) $0.45 \times 350 = 157$ @ \$5,000	\$785,000
Patients with polyps which will develop colorectal cancer (up to 35%) $0.35 \times 796 = 279$	
Of these 55% will be found at an advanced stage (153)	\$5,355,000
and 45% at an early stage (126)	\$630,000
Cancer deaths 276 (est.)	TOTAL COST
	\$13,525,000

Saving by Occult Blood Screening Program  
Lives Saved 159 (est.) \$2,471,000

Annual Program

Annual Cost \$442,000

V. C. 1.

Florida Cancer Care Program, Inc.  
a.k.a.  
Cancer Care Network of Florida (CCNF)

Herbert Kerman, M.D.  
Daytona Community Cancer Program

**Purpose:** To provide a comprehensive functional program of cancer care, control and research for the citizens of Florida through a cooperative consortium of Florida community hospitals, medical academic institutions, scientific and professional organizations and health care professionals incorporated as a private, nonprofit group whose Board of Directors establish policies and exercise control of activities; directed by a fulltime medical director and professional staff.

**Organizational Concept:** A voluntary, nonprofit, corporate structure utilizing existing institutions with established accredited cancer programs with coequal representation, has been formed to provide a free-standing entity. This network is charged to carry out functional programs involving all the cancer intervention areas. The network has been incorporated and currently consists of 15 Active Members, 14 Affiliate Members, 5 Associate members and 8 Supporting Members, which comprises over 200 professionals involved in every aspect of cancer care and control serving approximately 10,000 institutional beds in 29 hospitals and centers throughout the State of Florida and providing care and support for over 23,000 patients and their families annually.

**Programs & Activities:** The program is devoted to a wide scope of activities relating to cancer care, control and research. The program coordinates or provides:

1. A statewide network of clinical cancer research involving academic centers, community hospitals and comprehensive cancer centers.
2. A statewide cancer data system.
3. Patient advocacy in dealing with planning and regulatory agencies, state and federal government, third party payers, and other organizations whose decisions affect the quality of cancer care in Florida.
4. A statewide system of voluntary sharing of cancer resources and information among Florida health professionals and institutions.
5. Assistance and consultation to community hospitals in defining and developing cancer programs which meet or exceed the requirements established by the American College of Surgeons Commission on Cancer and in the development of additional or specialized cancer care components.
6. Provide support and assistance for cancer educational programs appropriate to the needs of the Florida health care community and, specifically, facilitates a cancer related allied health professional educational system.
7. Facilitates basic non-clinical cancer research, including participation in regional and statewide epidemiological studies.

**Present Activities:** With continued support from the Florida Division of the American Cancer Society, a pilot project under the aegis of the CCNF is underway to assess the requirements for a statewide program for early identification, screening and followup for first order female relatives of patients with carcinoma of the breast. This surveillance of individuals known to be at high risk has significant potential to impact upon reduction of morbidity and increased survival, the goal of cancer control. The pilot study is now nearing completion.

Annual program	Annual Core Grant \$ 250,000.00
	Annual Programs \$ 500,000.00



Jeffrey P. Krischer, Ph.D.  
University of Florida

Cancer is the leading cause of death in children due to disease. Unlike cancer in adults, childhood cancer requires centralized treatment in centers that are specially equipped and experienced. The realization of the dramatic improvements in survival and quality of life made possible through aggressive patient care necessitates multi-disciplinary professional input. Heretofore, the availability of such specialized services has been extremely limited and patients and their families have had to travel long distances to avail themselves of the latest in patient care. More recently, a network has been established within the State to provide access to the latest advances in treatments and new, multi-modal approaches towards patient care. Continued surveillance and monitoring needs to be done to ensure that these specialized services are available to more children within the State. For example, only 46% of children who are funded through the Children's Medical Services Program are followed on treatment protocols of the Pediatric Oncology Group. A larger percentage of children followed on treatment protocols and the continued availability of such protocols within the State needs to be assured.

In addition, we note that the latency period (i.e., the time from the initial carcinogenic effect and the appearance of the disease) is relatively short in children, giving rise to the opportunity to investigate etiologic factors that may be related to adverse environmental effects. These might include exposures during pregnancy, parental smoking, and exposures in the workplace. Preliminary investigations are underway in Hodgkin's Disease, soft tissue sarcomas and Wilm's Tumor. Continued investigations are necessary to identify those factors amenable to intervention to reduce the childhood cancer incidence.

In recognition of the unique aspects of childhood cancer, the legislature of the State of Florida has passed bills that pertain to the monitoring and evaluation of childhood cancer programs in the State of Florida. The Florida Association of Pediatric Tumor Programs has been specifically designated in this legislation. Funds are needed for the continued development of specialized treatment centers and for epidemiologic cancer control activities.

Annual project

Annual cost \$ 400,000.00

Medical Care Delivery of Control Services  
as a Risk Factor for Invasive Cervical CancerDale C. Chitwood, Ph.D.  
Clyde B. McCoy, Ph.D.  
University of Miami

The principle objective is to test the hypothesis that failure of the medical care system to deliver cancer control services is a risk factor for all stages of primary invasive cervical cancer. The Florida Cancer Data System will be used to identify all primary cases of invasive cervical cancer in selected demographic areas during successive one year periods. A comparison will then be made to a sample of non-cases from the same demographic areas who have been matched on age and time of ascertainment. All subjects will be interviewed to collect information on the exposure of interest (defined by utilization of Papanicolaou smears and follow-up services by the study participant). In addition to utilization, the availability, accessibility, and acceptability of cervical cancer control services will be assessed as well as the mode of delivery (health maintenance organization, fee for service, public health, etc.). Finally, other known or suspected risk factors for cervical cancer including age at first intercourse, number of sexual partners, contraceptive methods, cigarette smoking, Herpes simplex (II) virus infection and several dietary factors including vitamin A, carotene and vitamin C will be analyzed.

With respect to the question of primary interest, if cases and non-cases have the same distribution of cancer control service utilization, we may (tentatively) infer that differences as to classification into case or non-case cannot be explained by differences in exposure to this factor. On the other hand, if the proportion of cases having cervical smears is significantly lower than among non-cases or if cases are less likely to use follow-up services, we may infer a deleterious effect from failure of the medical care system to achieve utilization of screening and/or follow-up. Because an incidence survey is included in the proposed case-control design, the computation of risk-factor specific absolute estimates of cervical cancer frequency will be possible. Further, since information as to availability, accessibility and acceptability of control services as well as known and suspected biological risk factors for developing the disease will also be obtained, several supplemental hypotheses can be tested, yielding a description of the circumstances under which the strength of a possible cause-effect relationship with under-utilization of control services varies (i.e. interaction).

Three year project

Annual cost \$ 80,000.00

V. C. 4 Investigation of Health Care Utilization, Risk Factors  
and Disease Among Hispanics in Florida

Edward J. Trapido, Sc.D.  
Dale C. Chitwood, Ph.D.  
Clyde B. McCoy, Ph.D.  
Papanicolaou Comprehensive Cancer Center

The purpose of the proposed studies is to determine the health care utilization and disease patterns, and risk factors for disease among Hispanics. Specifically, we will determine whether Hispanics experience higher rates of cancer of certain sites than non-hispanics, and if so, what anatomic sites and subgroups of individuals are most severely elevated. In order to do this, we propose to assess the use of health care providers and facilities by Hispanics to determine if lack of access, type of care available or attitudes about medical care and screening account for differences in incidence of disease or subsequent survival. We also intend to determine the prevalence of behaviors among Hispanics which are etiologically linked to cancer, (i.e. tobacco, diet or alcohol use) since some of these are potentially mutable, and thus provide the possibility for prevention of malignant disease.

Two year project

Annual cost \$ 70,500.00

V. C. 5. Clinical and Investigative Program in Bone Marrow  
Transplantation for the State of Florida

Roy S. Weiner, M.D.  
University of Florida

Over the past quarter of a century bone marrow transplantation has proven to be efficacious in the treatment of hematologic malignancies and in patients with bone marrow failure (aplastic anemia). Successful treatment of malignant disease with bone marrow transplantation depends on two factors: 1) the use of effective systemic anticancer therapy that has the potential of eradicating endogenous malignancy and 2) the use of effective means of reconstituting the hematologic and immunocompetence of the patient after treatment. Effective systemic therapy is being developed for increasing numbers of tumors. Great advances are being made in reconstituting the hematologic and immunocompetence of the patient. Allogeneic bone marrow transplantation provides two definable therapeutic advantages and a number of research challenges. First the bone marrow used to reconstitute the patient is, a priori, free of tumor. Secondly, there is the potential that the immunocompetence of the transplanted marrow can have a therapeutic effect against the patient's residual tumor. The research challenges in allogenic transplantation include manipulating the patient in order to accept the "foreign" bone marrow and subsequently controlling the reaction of the "foreign" bone marrow against the patient (graft-versus-host disease). Research projects within the bone marrow transplantation program at the University of Florida and internationally are addressing these two issues and significant progress is being made. New immunosuppressive agents are being developed and used in the recipient and innovative ways of manipulating the donor bone marrow to minimize or avoid graft-versus-host disease are being developed. As progress proceeds in these problems, a wider spectrum of diseases will be amenable to bone marrow transplantation for cure and a larger number of patients will be candidates for the procedure. With respect to autologous bone marrow transplantation there is the obvious advantage of avoiding a genetic barrier to reconstitution by using the patient's own bone marrow which has been harvested, cryo-preserved and available for reinfusion after intensive cytotoxic therapy. The successful use of autologous bone marrow transplantation can potentially make intensive therapy available to every patient with malignant disease. The research challenges involved with autologous bone marrow are several: 1) adequate storage of bone marrow to assure viability after reinfusion, 2) the detection of minimal tumor in order to assure that the bone marrow of the patient is free of tumor at the time of reinfusion, 3) methods to purge the bone marrow of tumor cells in those patients who have tumor involvement of the bone marrow. The bone marrow transplantation program at the University of Florida has made significant progress in all three of the aforementioned research challenges. Active research efforts are continuing in each of those areas with anticipated advancement of knowledge and refinement of technique to further expand the application of bone marrow transplantation.

This is a state resource. The Bone Marrow Transplantation Program was formally founded in 1981 and has, since its inception transplanted more than 70 patients, three quarters of whom were residents of Florida. The Bone Marrow Transplantation Program requires an interdisciplinary effort for successful service and productive therapeutic research. A detailed budget has been prepared to staff the University of Florida Bone Marrow Transplantation Program. The needs are as follows: 15 new full time positions at an estimated annual salary of \$450,000; 6 new training positions at an estimated annual salary of \$120,000; materials and supplies \$80,000; operating capital outlay \$30,000.

Annual program

Annual cost \$ 680,000.00

Roy S. Weiner, M.D.  
Jeffrey P. Krischer, PH.D  
University of Florida

Published studies have shown that patients treated on research protocols, generally under the auspices of cooperative groups, fair better than those who are not. In addition, participation in group studies provides for a critical review of the state-of-the-art to develop a standardized therapeutic approach as well as pursuit of the most innovative and promising new treatment alternatives. The program in technology transfer is directed at making available to physicians in private practice throughout the state group protocols and the opportunity, in some instances, to actively participate in groups through the Community Clinical Oncology Programs or Cooperative Group Outreach Programs supported by the National Cancer Institute. The objective is to provide access and education in the use of state-of-the-art therapies to ensure that the most recent advances in management of all forms of cancer are available to the population of the State of Florida. The use of protocols in patient management serves as a means by which the latest advances are transferred to the private practitioner, where most cancer is managed. In addition, they serve as educational medium through which decisions on treatment modifications, dose escalation or reductions and the required levels of patient support can be appraised. Such a program has worked effectively within the State of Florida for pediatric malignancies and the State is in need of expanding it to include cancers occurring in all age groups. Through opportunities made available by the National Cancer Institute, the program envisions applying for Federal funding to supplement or replace State funding and increase participation in cooperative groups. This more active level of participation also provides for a built-in system of quality assurance and peer review to ensure the best care available.

Annual program

Annual cost \$ 250,000.00

VI. A.

Evaluative Comparisons of Special Programs--  
for the Deterrence and Delay of Smoking Among Youth

Clyde B. McCoy, Ph.D. et al  
University of Miami

The proposed research will test the general hypothesis that specialized school curriculum programs are effective in deterring smoking initiation among youth. The interventions consist of differing school health education and specialized programs that have been designed to deter smoking among youth. The specialized programs would consist of three separate programs, all of which have been used extensively in schools but which have not received the type of long-term evaluation that would allow conclusive evidence of which was most effective in the deterrence of smoking for long periods of time after completion of the programs. These specified intervention programs would be 1) the American Cancer Society Smoking Curriculum, 2) the curriculum of the CDC which consist of the primary grades curriculum project and the school health curriculum project, and 3) the Know Your Body Program designed by the American Health Foundation. Schools across the State of Florida will be randomly selected for experimental and control schools. The experimental school would receive the intervention whereas the equivalent control school would not. Such an experimental design would compare the effectiveness of the experimental schools to determine whether the experimental schools were more effective than the control schools, whether one of the three experimental programs was more effective than others and whether comparative effectiveness of the intervention is greater with specific subgroups of the population e.g., race, sex, ethnic, social economic status. The study would also investigate the factors that seem to motivate students who smoke despite interventions and detail the process by which the program components are most effective. A most important component of this research is to follow the students once they have completed the programs and compare them to control students who are also followed to determine the long-term retentive effects of the programs. The students would receive an annual assessment once they have completed the program. This design would also allow even more long term follow-up of a randomly selected sample of these students once they have completed school to determine the effectiveness of the program upon deterrence of smoking once the students have completed school and entered new life statuses.

A cancer control program must give high priority to research evaluating smoking prevention efforts to determine their efficacy as effective interventions to reduce the risk of cancer. Doll and Peto state: "No single measure is known that would have as great an impact on the number of deaths attributable to cancer as the reduction in the use of tobacco or a change to the use of tobacco in a less dangerous way. The principle impact would be on the incidence of cancer of the lung, but a material effect would also be produced on the incidence of cancers of the mouth, pharynx, larynx, esophagus, bladder, probably the pancreas and perhaps the liver." These conclusions are supported by numerous research studies which are reviewed in recent Surgeon General's Reports.

Given the strong evidence linking lung and other cancers with cigarette smoking and given the reported low success rate of cessation efforts directed at confirmed adult smokers, it is logical to focus cancer control efforts regarding smoking prevention on youth who have not yet initiated smoking or who have not yet established regular smoking habits. The majority of such efforts are incorporated as components of these education curricula. Few have been evaluated for effectiveness in deterring smoking behavior, especially as the students enter the prime initiation period of early high school. There is a major lacunae of scientifically sound research which yields knowledge regarding the actual effectiveness of specific prevention efforts on smoking behavior.

Five year project

Annual cost \$ 240,000.00

Jeffrey P. Krischer, Ph.D.  
University of Florida

Studies in the State of Florida have shown that individuals often ignore the early warning signs of cancer. Their delay in seeking medical care sometimes leads to detection when the cancer is already progressed to an advanced stage. Since advanced stage disease has a much more unfavorable outlook, both in terms of morbidity and mortality, we propose a program to address those delays in seeking medical care. The program will focus on an educational and media approach, making the public more aware of cancer's early warning signs and to improve access to medical facilities to reduce the period of delay. The program will pursue two parallel, yet interlocking strategies. In one, patients already presenting with advanced disease will be interviewed to ascertain the interval of time between the date when symptoms first appeared and when they sought medical treatment. For those in which there was a significant delay, factors leading to that delay will be studied. This information will be utilized in the public education aspect of the program, directed at making the population of the State of Florida more aware of cancer's early warning signs and the fact that, if detected early, many forms of cancer can be cured. The program would be developed in concert with volunteer agencies, such as the American Cancer Society, and utilize the available public service announcement spots throughout the radio and television media as well as other forums in which the public can be reached. Targeted interventions will be made among certain high risk groups (e.g., women over 50 for breast cancer) or high risk geographic areas.

Annual program

Annual cost \$ 175,000.00

To encourage and foster scientific research in basic knowledge of cancer by qualified individuals and institutions, grants of money or contracts may be made and the research will be conducted according to the highest standards pertaining in these areas and in accordance with practices acceptable to the scientific community. Grants will be made in support of research projects to non-profit institutions for higher learning in Florida and not to individuals, although the application will be made in behalf of the investigator and the evaluation made on the merits of the project and the qualifications of the investigator.

Annual Program

Annual Cost \$ 2,000,000.00



F.Ahmad, Ph.D. et al  
Papanicolaou Comprehensive Cancer Center

Objective: To understand the underlying biochemical difference(s) between normal and neoplastic mammary tissue

Previous work from this laboratory has shown that the induction of two key lipogenic enzymes, acetyl CoA carboxylase (ACC) and fatty acid synthesis (FAS), which normally occurs during the lactogenic differentiation of mammary gland is not observed in mammary adenocarcinomas even when the tumors are carried in animals of suitable physiological state (pregnant and lactating). In order to understand the biochemical basis of this aberrant regulation, studies are in progress to identify the biological effectors (hormones, nutrients and chemicals), which induce ACC and FAS in normal mammary epithelial cells, under in vitro conditions. It will then be feasible to establish whether or not these effectors engender similar effects on ACC and FAS in cell lines derived from dissociated mammary tumors.

In another study, we found that ACC of mammary neoplasms was distinct antigenically from its normal tissue counterpart. While ACC from lactating mammary tissue has been purified to apparent homogeneity, future studies will entail its purification from transplantable mammary tumors so that the nature of the chemical difference existing between normal and neoplastic tissue carboxylase could be delineated. In addition, monoclonal antibodies against the two carboxylases are being produced. Because of their exquisite specificity, these monoclonal antibodies may provide reagents of practical value in detecting (diagnosing) mammary neoplasia.

Annual program

Annual cost \$ 100,000.00

VII. A. 2. Rodent Tumor Distributions in Southwest Florida

C.I. Noss. Sc.D.

College of Public Health, University of South Florida

The presence of phosphate rock in underlying strata in southern Florida was acknowledged prior to the turn of the century. However, the radiological activity associated with the phosphate deposits has only been recognized as a possible health hazard since large scale mining operations were initiated a few decades ago. As our technology has developed, resulting in more precise and accurate measurements, interest in the health impact from exposure to radionuclides has grown. Due to this interest, a number of questions concerning the protection of public health have arisen, including: (1) How much radioactivity emanates from unmined lands overlying the phosphate containing matrices? (2) To what extent are the natural exposure levels changed by man's influence? (3) How do these airborne and waterborne routes of exposure affect health status? It is this third question addressing the effect of radiation on health, to which this proposed research primarily pertains.

An approach to assessing health risk is to use animals as surrogates for human populations. Animal studies are often carried out in the laboratory, but small mammals existing in the wild would be the best indicator of health risk. These rodent populations proposed for study are in intimate contact with the radionuclide containing medium. Because their home ranges are limited, and exposures to radionuclides are maximized at or below the soil surface, where these animals reside, adverse health effects related to natural radiation are more likely to be detected.

Field surveys will be conducted in three areas: 1) unmined land overlying the Bone Valley Formation, 2) reclaimed land from which phosphate has been mined, and 3) control lands outside the phosphate mining areas. From initial site surveys, areas of varying background radiation will be identified. In these tracts of land, small mammals will be trapped.

The specimens, mostly mice of the *Peromyscus* species, will be examined and autopsied. Mammal data collected will include genus, age, sex, weight, radionuclide body burden and number and type of tumors. This preliminary study is designed to observe trends of tumor prevalence in small rodents. Assessment of health impact of radiation on these animals will be based upon the survey and laboratory measurements, and the statistical significance of the observed tumor prevalence compared to the expected tumor prevalence. Collection sites will be selected for similarity in habitat such that the least number of confounding variables will be introduced into this study. These data will demonstrate either a significant or no significant difference in tumor prevalence between control and treatment groups. If an increase in tumor prevalence is observed, the significance of site specificity and possible routes of exposure will be addressed. It is hoped that research will serve as a first step in evaluating the existence of human health hazards derived from radiation associated with phosphate deposits.

Two year project

Annual cost \$ 83,425

Z. Brada, Ph.D.  
M. Hill, Ph.D.  
N.H. Altman, V.M.D.  
University of Miami

We were able to demonstrate that massive administration of the otherwise naturally available amino acid methionine to rats preexposed to some carcinogenic substances (ethionine, fluorenylacetylamide, benzopyrene) inhibits promotion and progression of hepatocellular carcinomas and subcutaneous sarcomas. For the investigation of the mechanism of this phenomenon we selected NIH3T3 cells transfected with genomic DNA isolated from human bladder carcinoma T24 (J10 cells). The cells carry the human oncogene stably integrated in the chromosomal DNA, and display the transformed phenotype with a capacity for anchorage-independent growth in immunodeficient mice. When these cells were exposed to methionine, they lost the transformed phenotype and the characters of normal phenotype (before transfection) reappeared. These cells continuously propagated in methionine supplemented medium (J10met cells), unlike J10 cells grown in normal medium, progressively segregated the hu-H-ras-1 gene. Conclusive evidence for the loss of hu-H-ras-1 oncogene sequence was provided by subcloning the J10met cells. The oncogene sequence could no longer be found and a fraction of subclones were no longer tumorigenic when assayed in nude mice.

It is evident that the described phenomenon has theoretical importance and practical potential. The subject of this proposal is to investigate the mechanism of the methionine effect In Vitro. We are assuming on the basis of accumulated experimental evidence that the reversing process advances in three phases. In the first phase, the cells are reversed but methionine presence is needed for the maintenance of the reversed phenotype. During extended methionine treatment the reversion becomes permanent (second phase) and methionine is not needed for the maintenance of the normal phenotype. In the third phase, the reversed cells lose the transforming sequences. The process is triggered by methionine but its presence in the process is no more needed.

We assume that the sensitivity of the transformed cells to the methionine effect (in comparison to normal cells) is based on alteration of methionine metabolism produced by the transformation. This assumption is supported by numbers of studies demonstrating that in some experimental or human tumor lines (including hepatocellular carcinomas) the main methionine pathway in normal cells (transsulfuration) is decreased. It remains to be demonstrated that this can also be applied in the NIH3T3 cells system: J10 cells and J10met cells. The blockade of the transsulfuration pathway can result in the change of methylation index (ratio between SAM and SAHCy) in favor of SAHCy which is recognized as a potent inhibitor of transmethylation processes. Consequently, the methionine presence can inhibit the methylation of the "Cap" structure of mRNA which is responsible for the maintenance of the transformed state of cells. This process can be connected with the normalized transsulfuration which can make possible permanent changes in the methylation of DNA. The silencing of the sequences in DNA or the changes in methylation pattern of chromatin destabilizes the genome and the instability can end with segregation of silenced oncogene. The availability of a number of clones exhibiting different degrees of the assumed changes makes such comparative study very feasible.

In Conclusion: The possibility of intervention in the progression of malignancy In Vivo and In Vitro as proposed in the above study may have a profound theoretical impact and far reaching clinical consequences.

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Prostatic Adenocarcinoma remains a significant disease in men, particularly older populations. It is difficult to diagnose since many forms are "clinically silent". Prostatic tumors are composed of heterogenous cellular populations which compound the types of chemotherapy which must be utilized.

We are studying a rodent model of prostatic cancer which closely resembles the human disease. This model R3327 is a hormone-responsive, slow growing tumor with a heterogenous cellular population. This model has been used to isolate hormone receptors and tumor specific cellular markers. Several lines have been developed from R3327 which allow the study of individual tumor characteristics e.g., metastases. Our current studies are aimed at separating the tumors into discrete subpopulations and then using single and multiple treatment modalities. This approach along with the agar gel in vitro assay will help us to better understand why certain chemotherapeutic modalities succeed or fail.

Five year program

Annual Cost \$ 135,000

New Immunotherapeutic Strategies  
for the Management of Human Cancer

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## Rationale:

Conventional cytoreductive therapy in human cancer is rapidly approaching its ultimate potential. New approaches will depend on the development of other direct antitumor mechanisms. Antitumor monoclonal antibodies, cloned tumor necrosis factor and lymphotoxin as well as the various cloned interferons offer significant potential in this regard. In addition, the mobilization of indirect host-mediated mechanisms using cloned thymic hormones, lymphokines, monokines and immunorestorative drugs also offers significant potential. The combining of these approaches, in so far as they are synergistic, will constitute new immunotherapeutic strategies for preclinical and clinical testing at this Institution.

## Objectives:

1. To expand our model of human tumor xenografts in the athymic nude mouse.
2. To develop other mouse cancer models in addition to the Meth A Sarcoma to evaluate strategies (e.g. B 16 melanoma, lewis lung).
3. To integrate current immunopharmacologic information into the design and testing of combined strategies in these models.
4. To link these preclinical effects to corresponding clinical protocols to assess these strategies in patients with minimal or recurrent but not disseminated disease.

## Organizational Considerations:

The development is needed of working groups, like the Gyn/ovarian monoclonal antibody group already formed. Groups and flow patterns for a colorectal cancer and head and neck cancer are described. Breast, melanoma, and leukemia/lymphoma are other groups to be considered based on the presence of local talent expert in these problems. A group to select, administer and monitor the immunotherapy is proposed including Drs. Lyman, Lockey, and Hadden. A single integrated program (Medical Oncology/Immunology/Immunopharmacology) or two programs (Medical Oncology/Immunopharmacology and Clinical Immunology/Immunopharmacology) are under consideration for clinical and research training in this area. Under consideration are the recruitment of a medical oncologist/immunotherapist and a "mouse cancer doctor" (M. Chirogos from the NCI). Needed is, initially, approximately \$500,000 to implace the preclinical portion of the program. Need for subsequent clinical research funds will depend upon the success of the preclinical efforts. Industry support for clinical research is expected where specific products are involved.

Initial grant

\$500,000

To encourage and foster clinical research in cancer by qualified individuals and institutions, grants or contracts may be made and the research will be conducted according to the highest standards pertaining in these areas and in accordance with practices acceptable to the medical and scientific community. Grants will be made in support of clinical studies to non-profit institutions for higher learning in Florida and not to individuals, although the applications will be made in behalf of the investigator and the evaluation made on the merits of the project and the qualifications of the investigator.

Annual program

Annual Cost \$ 2,000,000.00

VII. C.

Epidemiological Research Fund

To encourage and foster epidemiological research about cancer by qualified individuals and institutions, grants of money or contracts may be made and research will be conducted according to the highest standards pertaining in these areas and in accordance with practices acceptable to the scientific community. Grants will be made in support of epidemiological research projects to non-profit institutions for higher learning in Florida and not to individuals, although the application will be made in behalf of the investigator and the evaluation made on the merits of the project and the qualifications of the investigator.

Annual Program

Annual Cost \$ 750,000.00





VII. C. 2.

Investigations of Cancers  
that Occur Excessively Among Blacks

Edward J. Trapido, Sc.D.

University of Miami

The objectives of this study are:

1. To elicit risk factors for cancers of the esophagus, pancreas, prostate and of multiple myeloma with emphasis on diet, prior medical history, use of alcohol and tobacco, prior radiation and drug exposure, occupation and demographic factors.
2. To determine whether the risk factors for these sites differ between blacks and whites
3. To determine whether identified risk factors vary by age and sex
4. To determine whether identified risk factors vary by geographic region
5. To determine whether there are biochemical markers of risk for these diseases that are measureable in blood, urine or saliva
6. To provide data and epidemiologic input to the originators of this project for hypotheses they wish to test

In addition, because of the diversity within the black community of Dade County, we would like to determine how risk factors for these diseases vary between U.S.-born blacks and Caribbean born blacks, since the two groups may differ in terms of life style, diet, alcohol and tobacco use, prior medical history, and access to medical care.

Four year project

Annual cost \$ 350,000.00

VII. C. 4. A Case Control Study of Cervix Cancer in Latin Women

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A case control study of cervical cancer among hispanic women will be performed in Florida. Previous studies have shown that the use of black tobacco, a variety of home grown tobacco in Cuba, is even more strongly linked with lung cancer than American tobacco.. Since recent evidence suggests that cervical cancer risk is elevated by smoking, a study of cervical cancer focusing on black tobacco use is needed.

The study will focus largely on Cuban-Americans, studying both the descriptive epidemiology of the disease and etiologic factors. Approximately 200 incident cases of cervical cancer will be enrolled over a four year period, from 10 hospitals in Florida. Medical records and histologic slides from cases will be reviewed for information on disease, and cases and controls will be interviewed for information on suspected risk factors. Two controls per case will be selected from women admitted for non-chronic conditions, matched to the cases on age, race, ethnicity, hospital and date of admission. In addition, the husband (or current sexual partner) of both cases and controls will be identified and interviewed separately, to gain additional information on potential etiologic variables. The interviews of cases, controls and husbands/partners will also focus on demographic information (particularly with regard to migration) and sexual, contraceptive and medical histories, as well as on diet and alcohol use.

Five year project

Annual cost \$ 280,000.00

VII. C. 5. Cigarette Smoking and the Risk of Breast Cancer

Heather G. Stockwell, Sc.D., College of Public Health  
Gary H. Lyman, M.D., M.P.H., College of Medicine  
University of South Florida

It has been suggested by some that cigarette smoking might reduce the risk of breast cancer by lowering of the age of menopause of smoking women. However, as components of cigarette smoke have been detected in breast fluids, a mechanism may also exist for an increased risk of breast cancer associated with cigarette smoking.

In a preliminary study, using data available from the Florida Cancer Data System, Stockwell and Lyman found an increased risk of breast cancer among cigarette smokers. The risk was greatest among women aged fifty and over and among those smoking more than two packs of cigarettes a day. The data suggested a 60% increase in breast cancer risk among these women. In this study the smoking habits of women with breast cancer were compared to those of women of the same age, race and marital status who had cancers considered unrelated to cigarette smoking.

Given the significance of a possible increased risk of breast cancer among cigarette smokers, it is important to confirm these findings in a population of healthy women living in the same general environments as women who develop breast cancer.

Cigarette smoking has, in the past, been linked to a number of cancers in women including lung, bladder and stomach. Breast cancer is the most frequently occurring cancer among women in Florida today. Many of the risk factors for breast cancer such as parity, occurrence of benign breast disease and a family history of breast cancer are not easily altered. If cigarette smoking is associated with breast cancer, preventive measures are possible through alteration of smoking habits.

Although the relative risks associated with cigarette smoking are less for breast cancer than for lung cancer, the higher incidence of female breast cancer suggests a significant potential impact of cigarette smoking on the number of breast cancer cases in Florida.

Three year project

Annual cost \$ 102,833