

***** NOTICE OF GRANT AWARD *****
RESEARCH PROJECT COOPERATIVE AGREEMENT

Issue Date. 08/30/2002

Department of Health and Human Services
National Institutes Of Health
NATIONAL CANCER INSTITUTE



Grant Number: 5 U01 CA33193-21
Principal Investigator: RICE, JERRY M PHD
Project Title: EVALUATION OF CARCINOGENIC RISKS TO HUMANS

DIRECTOR, ADMIN & FINANCE
INTER AGENCY FOR RES ON CANCER
150 COURS ALBERT THOMAS
69372 LYON CEDEX 08
FRANCE

Budget Period: 09/01/2002 - 08/31/2003
Project Period: 09/01/1985 - 08/31/2005

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$530,437 (see 'Award Calculation' in Section I) to WORLD HLTH ORG INTL AGCY RES ON CANCER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,


Crystal Wolfrey

Grants Management Officer
NATIONAL CANCER INSTITUTE

See additional information below

SEP 03 2002

SECTION I - AWARD DATA - 5'U01 CA33193-21

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$294,800
Fringe Benefits	\$88,100
Personnel Costs	\$382,900
Consultant Services	\$50,000
Travel Costs	\$3,500
Other Costs	\$161,018
Federal Direct Costs	\$597,418
Federal F&A Costs	\$77,664
APPROVED BUDGET	\$675,082
Less Unobligated Balance	\$144,645
TOTAL FEDERAL AWARD AMOUNT	\$530,437

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project, is as follows.

22

(b)(5)

FISCAL INFORMATION:

CFDA Number: 93.393

EIN: 1900210016A1

Document Number: U1CA33193E

IC/ CAN / FY2002 / FY2003 / FY2004
CA/8423126 / 530,437 / (b)(5)

NIH ADMINISTRATIVE DATA:

PCC: 38CG3126 / OC: 41.4P / Processed: KEARSEJ 020827 0956

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 CA33193-21

For Payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 5 U01 CA33193-21

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Grant Award.
- The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Treatment of Program Income:
Additional Costs

INFORMATION This award is issued as a Cooperative Agreement, a financial assistance mechanism which requires cooperation between the awardee and the National Cancer Institute (NCI). The following Terms of Cooperation include the Programmatic Responsibilities of the Awardees, the Nature of Assistance by NCI Staff, Collaborative Responsibilities, and Arbitration Procedures (Attachment 1).

These special Terms and Conditions of Award are in addition to and not in lieu of otherwise applicable OMB administrative guidelines, Federal Regulations, including HHS Grant Administration Regulations at 42 CFR Part 52, 45 CFR Parts 74 and 92, and other HHS, PHS, and NIH Grant Administration policy statements.

The following administrative terms also apply:

INFORMATION This award utilizes as an offset the unobligated balance from the 19-year financial status report.

INFORMATION For administrative and management concerns, contact the Grants Management Specialist, Joy Kearse, at (301) 846-1010, kearsej@mail.nih.gov. For programmatic and scientific concerns, contact the Program Director, Dr. Davis Longfellow, at (301) 496-5471.

INFORMATION In a continuing effort to provide exceptional customer service, the NCI Grants Administration Branch has set up a Feedback address on its web site (<http://www.nci.nih.gov/admin/gab/index.htm>). General concerns and issues related to NCI grants policies, procedures, and practices can be sent to the Customer Liaison using this feature. Specific questions or concerns related to this grant should be addressed to the Grants Management Specialist listed in the Terms of Award.

DAVID G. LONGFELLOW, Program Official
Phone: 301-496-5471 Email: dl58s@nih.gov Fax: 301-496-1040

Joy Kearse, Grants Specialist
Phone: 301-846-1010 Email: kearsej@mail.nih.gov

SPREADSHEET

GRANT NUMBER: 5 U01 CA33193-21

P.I.: RICE, JERRY M

INSTITUTION: WORLD HLTH ORG INTL AGCY RES ON CANCER

	YEAR 21	YEAR 22	YEAR 23
Salaries and Wages	294,800	(b)(5)	
Fringe Benefits	88,100		
Personnel Costs	382,900		
Consultant Services	50,000		
Travel Costs	3,500		
Other Costs	161,018		
TOTAL FEDERAL DC	597,418		
TOTAL FEDERAL F&A	77,664		
TOTAL COST	675,082		

YEAR 21 YEAR 22 YEAR 23

F&A Cost Rate 1
F&A Cost Base 1
F&A Costs 1

13.00%
597,418
77,664

(b)(5)

5 U01 CA33193-

Collaborative Terms of Award

Nature of Collaboration with NCI Staff

NCI has certain responsibilities in terms of this cooperative agreement which involve assistance, information support, and scientific collaboration.

1. Scientific Resource

Since the monographs on each chemical which appear in the volumes published by IARC are fundamentally an international information resource and data bank on carcinogenesis and evaluation of qualitative risk of chemicals to humans, NCI, in an assistance and cooperative role, provides information and data which assist IARC staff in the preparation of certain sections of the final monograph (Sections 1.1 to 2.3). Sections 3.1 to 4.3 are developed by the Working Groups which consist of international scientists who review all these documents at the time of the meetings (3 per year) in Lyon, France. The National Cancer Institute, through arrangements with a contractor will provide such assistance.

2. Planning for Meetings of the Working Group

The IARC project is one of international support with NCI being the USA supporter for the monograph and the Information Bulletins on the Survey of Chemicals Being Tested for Carcinogenicity. This bulletin is a listing of chemicals being tested in laboratories throughout the world. Under the Cooperative Agreement, NCI:

- a. Makes suggestions to IARC on types of chemicals that should be evaluated at the three planned working group meetings per year held in Lyon, France.
- b. Makes suggestions and gives assistance to IARC as to USA resource people who should attend and participate in Working Group meetings. Personnel from regulatory agencies and trade associations should attend as observers.

3. Program Involvement in Relation to Input from NCI

Under the section on scientific resources, reference was made to NCI input as to data on production, occurrence, analysis, and use of chemicals. NCI, also provides information relevant to carcinogenicity on chemicals tested in U.S. laboratories. These data are then incorporated in the Information Bulletin on the Survey of Chemicals Being Tested for Carcinogenicity.

Collaborative Terms of Award

In discussing certain phases of work that involve assistance and collaboration on the part of the NCI with IARC, reference was made to the essentiality of effective liaison and support. Participation by the NCI Program Director in the working group meetings in Lyon, France could be either as an observer or as a representative of NCI or as a full member of the working group in his personal capacity as a scientist.

4 Reporting Requirements

NCI wishes to continue a semi-annual reporting requirement with scheduling or due dates for reports worked out by mutual arrangement between NCI staff and the IARC principal investigator. The volumes of monographs, supplements and survey bulletins are actually exhibits of achievements and accomplishments. Consequently, the semi-annual reports should dwell on planning, participation, selection of chemicals, problems of interfacing and cooperation and logistical matters. In addition, an annual report to be included in the required continuation applications should reflect that the project continues to conform to the purposes, objectives, and conditions of the award and has substantial programmatic involvement by NCI with the performer of the project.

5 Publication and Distribution

One of the significant features of the IARC project in development of this international, authoritative reference source is the publication and distribution, on a world-wide basis, of these volumes, including the supplements to the volumes listing Chemicals and Industrial Processes Associated with Cancer in Humans, as well as the Survey Bulletins.

The National Cancer Institute will receive approximately 400 copies of each volume published. The NCI distributes these copies to NCI staff, representatives of other agencies interested in environmental and occupational carcinogenesis, selected university scientists engaged in carcinogenesis research, public health organizations and medical libraries. Therefore, many organizations and scientists in the USA and abroad benefit from this program, which is partially supported by the National Cancer Institute.

Department of Health and Human Services
Public Health ServiceReview Group
NCI-E (M1)Type
5Activity
U01Grant Number
CA 33193-21Application JUN 21 2002
for Continuation Grant

Total Project Period

From: 09/01/1985

Through: 09/31/2005

Requested Budget Period

From: 09/01/2002

Through: 08/31/2003

To be verified by applicant. Check information in Items 1 through 6. If incorrect, furnish correct information in Item 13.

1. TITLE OF PROJECT

EVALUATION OF CARCINOGENIC RISKS TO HUMANS

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)

RICE, JERRY M
INTER AGENCY FOR RES ON CANCER
CARCINOGEN IDENT & EVALUATION
150 COURTS ALBERT THOMAS
69372 LYON CEDEX 08
FRANCE,

4. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)

INTER AGENCY FOR RES ON CANCER
150 COURTS ALBERT
69372 LYON CEDEX 08
FRANCE

2b. E-MAIL ADDRESS

RICE@IARC.FR

5. ENTITY IDENTIFICATION NUMBER

1900210016A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
CARCINOGEN IDENT & EVALUATION

2d. MAJOR SUBDIVISION

3. ORGANIZATIONAL CODE

60 OTHER RESEARCH ORGANIZATION

6. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
DIRECTOR, ADMIN & FINANCE
INTER AGENCY FOR RES ON CANCER
150 COURTS ALBERT THOMAS
69372 LYON CEDEX 08
FRANCE

E-MAIL ADDRESS hay@iarc.fr

Complete the following (see instructions).

7. HUMAN
SUBJECTS☒ No
☐ Yes

7a. If "Yes," Exemption no.

or

IRB approval date

☐ Full IRB or
☐ Expedited
Review7b. Assurance of
compliance no.8. VERTEBRATE
ANIMALS☒ No
☐ Yes8a. If "Yes,"
IACUC approval
date8b. Animal welfare
assurance no.

9. COSTS REQUESTED FOR NEXT BUDGET PERIOD

9a. DIRECT \$ 597,418

9b. TOTAL \$ 675,082

10. INVENTIONS AND PATENTS (See instructions)

☒ No ☐ Yes If "Yes," ☐ Previously
reported ☐ Not
previously
reported

11. PERFORMANCE SITE(S) (Organizations and addresses)

International Agency for Research
on Cancer
150 cours Albert Thomas
69372 Lyon Cedex 08
France12a. PRINCIPAL INVESTIGATOR OR
PROGRAM DIRECTOR (Item 2a)

Rice, Jerry M.

AREA
CODE

+33

TELEPHONE NO.
AND FAX NO.

472 73 84 76

+33

472 73 83 19 (fax)

12b. NAME OF ADMINISTRATIVE
OFFICIAL (Item 6)

Hay, Valerie

+33

472 73 84 67

+33

472 73 85 75 (fax)

12c. NAME AND TITLE OF OFFICIAL
SIGNING FOR APPLICANT
ORGANIZATION (Item 15)

Kleihues, Paul

+33

472 73 86 84

+33

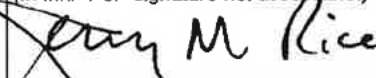
472 73 85 75 (fax)

E-MAIL ADDRESS kleihues@iarc.fr

13. USE THIS SPACE FOR CORRECTIONS TO ITEMS 1 THROUGH 6. INDICATE THE NUMBER(S) WHERE ANSWERS APPLY.

Item 6: e-mail address = hay@iarc.fr


14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI / PD NAMED IN 2a
(In ink. "Per" signature not acceptable.)

DATE

14 June 2002

15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 12c
(In ink. "Per" signature not acceptable.)

DATE

16 June 2002

DETAILED BUDGET FOR NEXT BUDGET PERIOD—DIRECT COSTS ONLY	FROM	THROUGH	GRANT NUMBER
	09/01/02	08/31/03	CA 33193-21

PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Rice, J.	Principal Investigator	(b)(4), (b)(6)	(b)(4), (b)(6)			-
Baan, R.	Scientist			78,800	23,500	102,300
Straif, K.	Scientist			76,800	23,000	99,800
Grosse, Y.	Scientist			49,300	14,700	64,000
Secretan, B.	Technical officer			11,300	3,400	14,700
McGregor, D.	Scientist			8,500	2,500	11,000
Lêzère, M.	Secretary			41,300	12,400	53,700
Egraz, S.	Archivist			28,800	8,600	37,400
SUBTOTALS				294,800	88,100	382,900

CONSULTANT COSTS See page 5 50,000

EQUIPMENT (Itemize)

SUPPLIES (Itemize by category)

TRAVEL One trip by principal investigator to USA for a scientific meeting and to consult with NCI program officials. 3,500

PATIENT CARE COSTS INPATIENT
OUTPATIENT

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)
See page 5 161,018

SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD \$ 597,418

CONSORTIUM/CONTRACTUAL COSTS DIRECT COSTS
FACILITIES AND ADMINISTRATION COSTS

TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (Item 9a, Face Page) \$ 597,418

Budget justification		Grant Number CA 33193-21	
Name, title and Unit or Programme*	Time on programme	Cost to NCI	Function
J.M. Rice, Chief, CIE	(b)(4), (b)(6)	None	Principle investigator. Overall planning and running of the monographs; selection of priorities for future consideration and selection of experts.
R. Baan, Scientist, CIE		100%	Assistance with planning, organization and implementation of meetings. Preparation and checking of monograph sections on other relevant data and genetic effects.
Y. Grosse, Scientist, CIE		100%	Assistance with planning, organization and implementation of meetings. Preparation and checking of monograph sections on animal carcinogenicity.
K. Straif, Scientist, CIE		100%	Assistance with planning, organization and implementation of meetings. Preparation and checking of monograph sections related to epidemiologic studies.
C. Partensky, Technical editor, CIE		None	Collection of exposure data, checking of monographs for accuracy prior to publication.
B. Secretan Technical Officer, CIE		25%	Assist in checking of Monograph sections on genetic effects and other relevant data
S. Egraz Archivist, CIE		100%	Maintaining an index and files of publications for IARC Monographs; survey of literature and collection of data on substances already considered by previous working groups.
M. Lézère, Secretary, CIE		100%	Entry of draft monographs onto word processors; production of final monographs for printing.
J. Mitchell, Technical assistant, CIE		None	Entry of draft monographs onto word processors; formatting and revision of English; production of monographs during meetings.
E. Perez, Secretary, CIE		None	Administrative organization of working group meetings.
P. Boffetta, Chief, ECE		None	To advise on sections on epidemiology.
E. Cardis,		None	To advise on evaluations of physical agents.

Chief, RCA	(b)(4), (b)(6)		
M. Friesen, Scientist, NTR		None	To advise on chemistry and analysis.
J. Hall-Posner, Chief, REP		None	To advise on DNA damage and repair.
D. McGregor ¹		100%	To assist with updating previous monographs.
N. Napalkov ¹		None	To assist with updating previous monographs

*CIE: Unit of Carcinogen Identification and Evaluation

ECE: Unit of Environmental Cancer Epidemiology

NTR: Unit of Nutrition and Cancer

RCA: Unit of Radiation and Cancer

REP: Unit of DNA Repair

¹ When actually employed, maximum 60 days

² Until 31 December 2001

BUDGET JUSTIFICATION

GRANT NUMBER

CA 33193-21

Provide a detailed budget justification for those line items and amounts which represent a significant change from that previously recommended.

CONSULTANT

- Preparation of draft Monographs
\$400/expert x 25 experts x 2 Monographs = \$ 20,000

- Editing of Monographs
\$15,000 per volume x 2 volumes = \$ 30,000
\$ 50,000

OTHER

- Working Groups (\$45,000 x 2) = \$ 90,000

- Printing of Monographs (\$18,000 x 2) = \$ 36,000

- Distribution costs of free Monographs (\$4,500 x 2) = \$ 9,000

- Reprint requests = \$ 10,000

- Books, journals and reproduction costs = \$ 10,018

- Information databases on CD-ROM = \$ 6,000

\$161,018

CURRENT BUDGET PERIOD	FROM	THROUGH
	09/01/2001	08/31/2002

Explain any estimated unobligated balance (including prior year carryover) which is greater than 25% of the current year's total budget or more than \$250,000.

	Total estimated expenditure & obligations	Estimated unobligated balance
Total direct costs	\$570,000	\$10,000
Indirect costs	\$ 74,100	\$ 1,300
TOTAL	\$644,100	\$11,300 (1.72%)

PROGRESS REPORT SUMMARY		GRANT NUMBER CA 33193-21	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Rice, Jerry M.		PERIOD COVERED BY THIS REPORT	
APPLICANT ORGANIZATION International Agency for Research on Cancer		FROM 09/01/2001	THROUGH 08/31/2002
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Evaluation of Carcinogenic Risks to Humans			
a Human Subjects (Complete Item 7 on the Face Page)			
Use of Human Subjects <input type="checkbox"/> Change <input checked="" type="checkbox"/> No Change Since Previous Submission			
b Vertebrate Animals (Complete Item 8 on the Face Page)			
Use of Vertebrate Animals <input type="checkbox"/> Change <input checked="" type="checkbox"/> No Change Since Previous Submission			
(SEE INSTRUCTIONS)			

a. Specific Aims of the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans are to critically review and evaluate the strength of the total published scientific evidence for carcinogenic risk from biological, physical, and chemical agents, complex mixtures, and environmental circumstances to which humans are exposed. Agents and exposures are classified by levels of evidence for human carcinogenicity, which range from *carcinogenic to humans* (Group 1) to *probably not carcinogenic to humans* (Group 4). These classifications are intended to guide and assist the development of strategies for cancer prevention. The long-term goal is to publish evaluations of all environmental agents suspected as causes of human cancer, and to re-evaluate those for which evidence was incomplete when previously reviewed, whenever new findings provide additional evidence that may change a previous evaluation. These aims have not been modified since the competing application dated 28 June 1999.

b. Studies and Results. Three working group meetings to prepare volumes 81, 82, and 83 of the IARC Monographs were completed during grant year 20 (1 September 2001 through 31 August 2002). Up-to-date lists of classifications, summaries of all evaluations, planned future activities, and related information have been posted on the Monographs website at <http://monographs.iarc.fr> where they are freely available as soon as each volume is printed. From volume 1 (1972) through volume 83 (2002), the Programme has evaluated 886 agents and exposures in the human environment for evidence of carcinogenicity, many of them more than once as new scientific evidence relevant to evaluations of carcinogenicity has been published. An electronic version containing the complete, corrected text of all Monographs ever published has now been prepared and is commercially available as CD-ROM (updated annually) and/or by internet subscription (updated after each new volume is printed) from GMA Industries, Inc., Annapolis, MD 21401 (<http://www.gmai.com>).

• **Volume 81 (9-16 October 2001), Man-made Vitreous Fibres (in press)**

This volume re-evaluates glass wool, rock wool, and related vitreous fibre materials that are used for thermal insulation in buildings, including private homes. It supersedes the previous Monographs volume 43 on this subject (1988) and specifically addresses the evolving concept that the carcinogenic hazard of inhaled vitreous fibres is directly related to persistence of the fibres in lung tissues. A brief summary of the meeting that has been posted on the Monographs website at <http://monographs.iarc.fr> is attached as Appendix 1. Invited participants in the meeting are listed in Appendix 2. Despite the aftermath of 11 September 2002, all working group members were finally able to attend, unfortunately, four invited observers from U.S. Government agencies were not able to do so.

GENDER AND MINORITY INCLUSION Provide the number of subjects enrolled in the study <i>to date</i> (cumulatively since the most recent competitive award) according to the following categories (See Page 9 for definitions). If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations which are included in the study.					Study Title		
	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	TOTAL
Female							
Male							
Unknown							
TOTAL							

- **Volume 82 (12-19 February 2002), Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene (in preparation)**

This volume evaluates certain traditional herbal medicinal preparations, including *Aristolochia* extracts, which are known to contain natural products that are carcinogenic to experimental animals. Chinese herbal preparations used in Western countries for weight-loss regimens have caused urothelial carcinoma, such mixtures are now classified in Group 1, carcinogenic to humans. The mycotoxin fumonisin B₁ and the industrial organic compounds naphthalene and styrene were also evaluated because of new data on carcinogenicity to experimental animals. A summary of the meeting from the Monographs website is attached as Appendix 3. Participants in the meeting are listed in Appendix 4.

- **Volume 83 (11-18 June 2002), Tobacco Smoke and Involuntary Smoking (working group meeting in progress)**

This volume will be a completely updated new edition of the previous Monographs volume 38 on Tobacco Smoking (1986), and will include the first explicit IARC Monographs evaluation of second-hand tobacco smoke. It will also include new information on intervention (smoking cessation), organ sites for tobacco-related cancers not previously identified with certainty, and a comprehensive review of the synergistic carcinogenic effects of tobacco smoke in combination with other agents including alcoholic beverages, asbestos, and radon. An outline of the meeting is attached as Appendix 5, and participants are listed in Appendix 6.

In addition, a scientific advisory group of invited participants on *Mechanistic Considerations in the Molecular Epidemiology of Cancer* was convened at IARC during 14-16 November 2001 under sponsorship of the Monographs Programme. The proceedings of that meeting will be published as an IARC Scientific Publication. (This meeting was not funded by this cooperative agreement, but is mentioned here for the sake of completeness in the overall description of the Programme)

c. Significance The evaluations published in the IARC Monographs are intended to assist national and international authorities to formulate carcinogenic risk assessments and to make risk management decisions, and to inform expert researchers as well as the general public regarding the evidence for carcinogenicity of environmental agents and exposures of all kinds.

d. Plans for the period 1 September 2002 through 31 August 2003 include two volumes of the *IARC Monographs*

- **Volume 84 (15-22 October 2002), Some Drinking Water Disinfectants and Contaminants, including Arsenic** This volume will supplement but not duplicate the previous Monograph (volume 52, 1991) on chlorination and its byproducts, and will evaluate chloramine, chloramidation, and certain chlorination byproducts not previously reviewed. It will also address the serious problem of arsenic in drinking water.

- **Volume 85 (11-18 June 2003), Some Cultural Habits other than Tobacco Use**

This volume will evaluate various non-tobacco cultural habits that appear to pose a carcinogenic risk. Special emphasis will be placed on habits that are practiced in certain developing countries, notably India.

In addition to the two Monographs working groups, two further meetings are planned during this period:

- A scientific meeting to prepare an IARC Scientific Publication on mycotoxins including aflatoxins and fumonisins and strategies for their control will take place in Lyon in November 2002. This effort is an outgrowth of Monographs volume 82 and its reviews of aflatoxins and fumonisins. It will take place jointly with other elements of the World Health Organization and the Food and Agriculture Organization of the U.N. (This meeting and the resulting publication will not be funded by this Cooperative Agreement, but is mentioned here for the sake of completeness in describing Monographs Programme activities for the year)
- An ad-hoc Scientific Advisory Group on priorities for future evaluations will be convened in Lyon in February 2003 to review nominations of chemicals and complex chemical mixtures for evaluation by the *Monographs* Programme during the next five years. Nominations will be solicited world-wide during the second half of 2002, making extensive use of the internet to reach the widest possible community of potential participants. (Like the scientific meeting described above, this meeting will not be funded by this Cooperative Agreement, but is mentioned here for the sake of completeness in describing Monographs Programme activities for the year)

Principal Investigator/Program Director (Last, first, middle): Rice, Jerry Mercer

e. Publications

IARC (2001) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 79: Some thyrotropic agents.

Bond, J.A., Albertini, R., Bird, M., Boogaard, P., Coggon, D., Elcombe, C., Garte, S., Gelbke, P., Himmelstein, M., Kaden, D., Levy, L., Lynch, J., Medinsky, M., Peltonen, K., Rice, J., and Swenberg, J. (Eds.): *Proceedings of the XXXVIII European Congress of Toxicology Satellite Symposium to Eurotox 2000 – Evaluation of Butadiene, Isoprene & Chloroprene Health Risks* – London, England, 12-14 September 2000. *Chem. Biol. Interactions* **135-136**, 2001, 713 pp.

Sonich-Mullin, C., Fielder, R., Wiltse, J., Baetcke, K., Dempsey, J., Fenner-Crisp, P., Grant, D., Hartley, M., Knaap, A., Kroese, D., Mangelsdorf, I., Meek, E., Rice, J.M., and Younes, M.: IPCS Conceptual framework for evaluating a mode of action for chemical carcinogenesis. *Reg. Toxicol. Pharmacol.* **34**, 146-152, 2001.

Rice, J.M., Wilbourn, J.D., and Turusov, V.S.: IARC Monographs: Evaluation of DNA topoisomerase II inhibitors and some other pharmaceutical drugs. *Herald of the N.N. Blokhin Cancer Research Center, Russian Academy of Medical Sciences* **1/2001**, 58-61, 2001.

Rice, J.M.: Diesel particulate emissions and other occupational hazards in mining. *Kompass (Zeitschrift für Sozialversicherung im Bergbau)* **111**: 46-51, 2001.

IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 80: Non-ionizing radiation, Part 1: Static and extremely low-frequency (ELF) electric and magnetic fields.

IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 81: Man-made vitreous fibres (*in press*).

IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 82: Some traditional herbal medicines, some mycotoxins, naphthalene and styrene (*in preparation*).

CHECKLIST

GRANT NUMBER

CA 33193-21

1. ASSURANCES/CERTIFICATIONS (See Instructions, Page 10)

The following assurances/certifications are made and verified by the signature of the OFFICIAL SIGNING FOR APPLICANT ORGANIZATION on the FACE PAGE of the application. If unable to certify compliance where applicable, provide an explanation and place it after this page.

• Human Subjects, • Vertebrate Animals, • Debarment and Suspension, • Lobbying, • Delinquent Federal Debt, • Research Misconduct, • Civil Rights (Form HHS 441 or HHS 690), • Handicapped Individuals (Form HHS 641 or HHS 690), • Sex Discrimination (Form HHS 639-A or HHS 690), • Age Discrimination (Form HHS 680 or 690), • Financial Conflict of Interest

2. PROGRAM INCOME (See Instructions, Page 10)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

3. FACILITIES AND ADMINISTRATION (F & A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office. F&A costs will **not** be paid on foreign grants, construction

grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, and specialized grant applications.

☐ DHHS Agreement dated _____

☐ No F&A Costs Requested

☒ No DHHS Agreement, but rate established with J. Wayne Berry, Accountant, DHHS Date 18 October 1983

CALCULATION*

Entire proposed budget period

Amount of base \$ 597,418 x Rate applied 13 % = F&A costs \$ 77,664

Add to total direct costs from form page 2 and enter new total on FACE PAGE, Item 9b

*Check appropriate box(es)

☐ Salary and wages base ☐ Modified total direct costs base ☒ Other base (Explain below)

☐ Off-site, other special rate, or more than one rate involved (Explain below) Total direct costs

Explanation (Attach separate sheet, if necessary)

PERSONNEL REPORT

GRANT NUMBER

Place this form at the end of the signed original copy of the application. Do not duplicate.

CA 33193-21

All Key Personnel for the Current Budget Period

Name	Degree(s)	SSN	Role on Project (e. g., PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
J. Rice	PhD	(b)(6)	PI	(b)(6)	(b)(4), (b)(6)
R. Baan	PhD	-	Scientist		
Y. Grosse	PhD	-	Scientist		
C. Partensky	M.Sc.	-	Technical editor		
K. Straif	MD, PhD	-	Scientist		