

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

Issue Date: 09/19/2001

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



Grant Number: 5 U01 CA33193-20
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: 09/19/2001 - 08/31/2002
Project Period: 09/01/1985 - 08/31/2005

r Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$655,420 (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,

A handwritten signature in dark ink, appearing to read 'Crystal Wolfrey'.

Crystal Wolfrey
Grants Management Officer
NATIONAL CANCER INSTITUTE

See additional information below

SECTION I - AWARD DATA - 5 U01 CA33193-20

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$260,900
Fringe Benefits	\$96,400
Personnel Costs	\$357,300
Consultant Services	\$50,000
Travel Costs	\$3,400
Other Costs	\$169,318
Federal Direct Costs	\$580,018
Federal F&A Costs	\$75,402
APPROVED BUDGET	\$655,420
TOTAL	\$655,420

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

21 (b)(5)
22
23

FISCAL INFORMATION:

CFDA Number: 93.393

EIN: 1900210016A1

Document Number: U1CA33193E

IC/	CAN	/	FY2001	/	FY2002	/	FY2003	/	FY2004
CA/8423126	/		655,420	/	(b)(5)				

NIH ADMINISTRATIVE DATA:

PCC: 38AI3133 / OC: 41.4P /Processed: WOLFREYC 010918 0323

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 CA33193-20

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 CA33193-20

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.)

This grant is excluded from Expanded Authorities.

Treatment of Program Income:
Other Research (Add/Deduct Option)

5 U01 CA 33193-20

TERMS OF AWARD

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 (1) the Programmatic Responsibilities of the Awardees, the Nature of Assistance by NCI Staff, Collaborative Responsibilities, and Arbitration Procedures (Attachment 1); and (2) the following administrative terms.

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.

INFORMATION This award includes funds for 12 months of support. The budget period start date has been delayed from 09/01/2001 to 09/19/2001 due to the NCI's late receipt of the financial status report for year 18; however, the expiration date of the budget period remains unchanged (08/31/2002). Allowable preaward costs may be charged to this award in accordance with the conditions outlined in the NIH Grants Policy Statement (March 2001)) and with institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps_2001/.

INFORMATION For administrative and management concerns, contact the Grants Management Specialist, Crystal Wolfrey, at (301) 496-8634, or via e-mail at crystal.wolfrey@nih.gov. For programmatic and scientific concerns, contact the Program Director, Dr. David 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.

Crystal Wolfrey, Grants Specialist 301-496-8634 wolfreyc@gab.nci.nih.gov

SPREADSHEET

GRANT NUMBER: 5 U01 CA33193-20

P.I.: RICE, JERRY M

INSTITUTION: WORLD HLTH ORG INTL AGCY RES ON CANCER

	YEAR 20	YEAR 21	YEAR 22	YEAR 23
Salaries and Wages	260,900	(b)(5)		
Fringe Benefits	96,400			
Personnel Costs	357,300			
Consultant Services	50,000			
Travel Costs	3,400			
Other Costs	169,318			

	YEAR 20	YEAR 21	YEAR 22	YEAR 23
TOTAL FEDERAL DC	580,018	(b)(5)		
TOTAL FEDERAL F&A	75,402			
TOTAL COST	655,420			

	YEAR 20	YEAR 21	YEAR 22	YEAR 23
F&A Cost Rate 1	13.00%	(b)(5)		
F&A Cost Base 1	580,018			
F&A Costs 1	75,402			

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 Service

Review Group	Type	Activity	Grant Number
NCI-E (M1)	5	U01	CA 33193-20
Total Project Period			
From: 03/01/1995		Through: 08/31/2005	
Requested Budget Period			
From: 03/01/2001		Through: 08/31/2002	

Application JUN 28 2001 for Continuation Grant

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

1903210016A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

CARCINOGEN IDENT & EVALUATION

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

2d. MAJOR SUBDIVISION

3. ORGANIZATIONAL CODE

63 OTHER RESEARCH ORGANIZATION

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
 Review
7b. Assurance of
compliance no.8. VERTEBRATE
ANIMALS
☒ No
☐ Yes
8a. If "Yes,"
IACUC approval
date8b. Animal welfare
assurance no.

9. COSTS REQUESTED FOR NEXT BUDGET PERIOD

9a. Direct \$ 580,000 9b. TOTAL \$ 655,400

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
France

12a. 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.

4 and 2a: 150 cours Albert Thomas; 2b: rice@iarc.fr; 6: 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.)

Jerry M. Rice

DATE

21 June 01

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.)

Paul Kleihues

DATE

21 June 01

DETAILED BUDGET FOR NEXT BUDGET PERIOD—DIRECT COSTS ONLY	FROM	THROUGH	GRANT NUMBER
	09/01/01	08/31/02	CA33193-20

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			71,600	22,000	93,600
Straif, K.	Scientist			55,000	37,000	92,000
Grosse, Y.	Scientist			44,400	13,600	58,000
Suonio, E.	Scientist			16,800	5,200	22,000
McGregor, D.	Scientist			11,000	-	11,000
Lézère, M.	Secretary			37,800	11,300	49,100
Egraz, S.	Clerk			24,300	7,300	31,600
SUBTOTALS				260,900	96,400	357,300

CONSULTANT COSTS 475448

See page 5 51820 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 4077 3,400 ✓

PATIENT CARE COSTS INPATIENT OUTPATIENT

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)

See page 5

SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD 157410 682375 \$ 580,000

CONSORTIUM/CONTRACTUAL COSTS DIRECT COSTS FACILITIES AND ADMINISTRATION COSTS

TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD (Item 9a, Face Page) \$ 580,000

Committee - SECURS DC
Total = 655420 B

Budget justification**Grant Number CA 33193-20**

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.
S. Egraz		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, Chief, RCA		None	To advise on evaluations of physical agents.

M. Friesen, Scientist, NTR	(b)(4), (b)(6)	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.
E. Suonio ²		100%	To assist with monograph sections on epidemiology.

*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 33193-20

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 =	<u>\$ 30,000</u>
	\$ 50,000

OTHER

- Working Groups (\$45,000 x 2) =	\$ 90,000
- Printing of Monographs (\$20,000 x 2) =	\$ 40,000
- Distribution costs of free Monographs (\$5,000 x 2) =	\$ 10,000
- Reprint requests =	\$ 12,300
- Books, journals and reproduction costs =	\$ 11,000
- Information databases on CD-ROM =	<u>\$ 6,000</u>
	\$169,300

CURRENT BUDGET PERIOD	FROM	THROUGH
	09/30/2000	08/31/2001

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.

	<u>Total estimated expenditure & obligations</u>	<u>Estimated unobligated balance</u>
Total direct costs	\$435,600	\$127,500
Indirect costs	<u>\$ 56,600</u>	<u>\$ 16,600</u>
TOTAL	\$492,200	\$144,100 (22.65%)

The unobligated balance is due to the fact that the post of epidemiologist, costed at \$114,400, was not filled during the current project period.

BIOGRAPHICAL SKETCH

Give the following information for all **new** key personnel
Copy this page for each person

NAME Straif, Kurt		POSITION TITLE Scientist (Epidemiologist)	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Bonn, Germany	B.Med.	1984	Medicine
Bonn University, Medical Clinic	M.D.	1987	Oncology, Occupational Medicine
UCLA School of Public Health, USA	M.P.H.	1991	Epidemiology, Biostatistics

RESEARCH AND PROFESSIONAL EXPERIENCE Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES

Sept 1984 – Aug 1990 Postgraduate Fellow in Epidemiology, Univ. of Bonn (Germany)
Oct 1991 – Mar 1995 Assistant Professor of Occupational Medicine, Univ. of Giessen
Apr 1995 – Sept 2001 Associate Professor of Epidemiology, Univ. of Muenster

List of Publications

Straif K (2001) Re: A meta-analysis of risk estimates for prostate cancer related to tire and rubber manufacturing operations. *J Occup Environ Med* (in press)

Straif K, Keil U, Taeger D, Holthennrich D, Sun Y, Bungers M & Weiland S K (2000) Exposure to nitrosamines, carbon black, asbestos, and talc and mortality from stomach, lung and laryngeal cancer among a cohort of rubber workers. *Am J Epidemiol* 152: 297-306

Taeger D, Sun Y, Keil U & Straif K (2000) A standalone windows application for computing exact person-years, standardized mortality ratios and confidence intervals in epidemiologic studies. *Epidemiology* 11: 607-608

Straif K, Weiland S K, Bungers M, Holthennrich D, Taeger D, Sun Y & Keil U (2000) Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers. *Occup Environ Med* 57: 180-187

Straif K, Chambless L, Weiland S K, Wienke A, Bungers M, Taeger D & Keil U (1999) Occupational risk factors for mortality from stomach and lung cancer among rubber workers: An analysis using internal controls and refined exposure assessment. *Int J Epidemiol* 28: 1037-1043

Straif K, Weiland S K, Bungers M, Holthennrich D & Keil U (1999) Exposure to nitrosamines and mortality from salivary gland cancer among rubber workers. *Epidemiology* 10: 786-787

Mundt K A, Weiland S K, Bucher A M, Straif K, Werner B, Chambless L & Keil U (1999) An occupational cohort mortality study of women in the German rubber industry, 1976 to 1991. *J Occup Environ Med* 41: 807-812

Straif K, Weiland S, Werner B, Wienke A & Keil U (1999) Elevated mortality from nonalcohol-related chronic liver disease among female rubber workers: Is it associated with exposure to nitrosamines? *Am J Ind Med* 35: 264-271

Sponholz G, Baitsch H, Ahr W, Harr H, Hoelzer M, Keller F, Meier Allmendinger D, Straif K & Allert G (1999) Genetic Medicine: A new Copernican turning point? In: Hanson M J & Callahan D, eds. *The Goals of Medicine: The Forgotten Issue in Health Care Reform*. Washington, Georgetown University Press. pp 162-173

PROGRESS REPORT SUMMARY		GRANT NUMBER CA 33193-20	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Rice, Jerry M.		PERIOD COVERED BY THIS REPORT	
APPLICANT ORGANIZATION International Agency for Research on Cancer		FROM 09/01/2000	THROUGH 08/31/2001
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 significant contributing environmental causes of human cancer, and to re-evaluate those for which evidence was incomplete at the time of initial evaluation 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. The competing application reported completion of IARC Monographs through Volume 75. The working group for volume 75 met during June 1999, and was the first working group convened during grant year 18. The following working group meetings to prepare subsequent volumes of IARC Monographs were (or will be) completed since submission of the competing application. This includes results for the rest of grant year 18 and all of year 19. 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> and are freely available.

Grant year 18 (03/01/1999 – 08/31/2000, extended to 18 months without additional funds)

- Volume 76 (12-19 October 1999). Some Antiviral and Antineoplastic Drugs, and Other Pharmaceutical Agents**
This volume addressed antiretroviral nucleoside analogs (including AZT), topoisomerase II inhibitors and some other agents. The topoisomerase II inhibitor and antineoplastic drug, etoposide, was classified *probably carcinogenic to humans* (Group 2A), and etoposide in combination with cisplatin and bleomycin was classified *carcinogenic to humans* (Group 1).
- Volume 77 (15-22 February 2000). Some Industrial Chemicals**
The 16 industrial organic compounds evaluated included the peroxisome proliferator, di-2-ethylhexyl phthalate (DEHP), which was reclassified downward to Group 3 (*cannot be classified as to carcinogenicity to humans*). This was on the basis of evidence on mechanisms of carcinogenesis by such substances, which have quantitatively different effects in experimental rodents versus humans.

GENDER AND MINORITY INCLUSION					Study Title		
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.							
	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 78** (14-21 June 2000) Ionizing Radiation Part II: Some Internally Deposited Radionuclides
Reactor accidents (including Chernobyl), iatrogenic disease from medical use of certain radionuclides, and other effects of α - and β -particle emitting radionuclides were considered. These yielded 9 new Group 1 evaluations, 7 of them specific to a single nuclide (and its decay products: if any ^{224}Ra , ^{226}Ra , ^{228}Ra , ^{232}Th , ^{239}Pu , ^{32}P , ^{131}I and other short-lived isotopes of iodine) and 2 of them global (to α - and to β -emitting internally deposited radionuclides respectively). The previous Group 1 evaluation of ^{222}Rn and its decay products was confirmed and updated.

Grant year 19 (09/01/2000 – 08/31/2001)

- **Volume 79** (10-17 October 2000) Some Thyrotropic Chemicals
Nineteen chemicals that induce tumours of thyroid follicular epithelium in rodents were evaluated. Three of these (amitrole, ethylenethiourea and sulfamethazine) were classified in Group 3 on the basis of mechanistic evidence that they induced thyroid tumours in rodents by hormonal mechanisms that did not predict human risk. A summary of the meeting that has been posted on the Monographs website at <http://monographs.iarc.fr> is attached as Appendix 1.

- **Volume 80** (19-26 June 2001) Static and Extremely Low Frequency Electromagnetic Fields
This is the first of a planned series of two Monographs volumes on non-ionizing radiation and will include evaluations of electromagnetic fields associated with electrical power lines, electric appliances, and electrical wiring in buildings. The outline for this meeting is attached as Appendix 2, and the list of participants in the meeting is attached as Appendix 3. The second meeting in this series, not yet definitely scheduled, will address radiofrequency electromagnetic fields: portable telephones and radar.

- A scientific advisory group consisting of the faculty of the *IARC Course on Infections and Infectious Agents in Human Cancer* (Annecy, France, 22-28 April 2001) met to consider what further evaluations of biologic agents and infectious processes should be undertaken in future IARC Monographs. The conclusions of that meeting are being prepared as an IARC Internal Report that will be published both in hard copy and on the Monographs website. (This meeting was not funded by the NCI cooperative agreement, but is mentioned here for the sake of completeness in describing programme activities for the year.)

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 2001 through 31 August 2002 include three volumes of the *IARC Monographs*.

- **Volume 81** (9-16 October 2001), Man-made Vitreous Fibres
This volume will re-evaluate glass wool, rock wool, and related vitreous fibre materials used for thermal insulation in buildings, including private homes. It will supersede the previous Monographs Volume 43 on this subject (1988) and will specifically address the evolving concept that the carcinogenic hazard of inhaled vitreous fibres is directly related to persistence of the fibres in lung tissues.

- **Volume 82** (12-19 February 2002), Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene
This volume will evaluate certain traditional herbal medicinal preparations including *Aristolochia* extracts, which are known to contain natural products that are carcinogenic to experimental animals and have been implicated as possible carcinogens in humans. Certain mycotoxins, especially fumonisin B₁, and the industrial organic compounds naphthalene and styrene will also be evaluated because of new data on carcinogenicity to experimental animals.

▪ **Volume 83 (11-18 June 2002) Tobacco Smoke**

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 evaluation of environmental 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.

▪ In addition, a scientific advisory group of invited participants on *Mechanistic Considerations in the Molecular Epidemiology of Cancer* will convene 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. (Like the advisory group meeting on infectious agents mentioned above, this meeting will not be funded by this cooperative agreement but is mentioned here for the sake of completeness.)

e. Publications

IARC (2000) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 76: Some antiviral and antineoplastic drugs, and other pharmaceutical agents

IARC (2000) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 77: Some industrial chemicals

Rice, J M & Wilbourn, J D (2000) Tumours of the nervous system in carcinogenic hazard identification. *Toxicol Pathol* **28**: 202-214, 2000

McGregor, D B, Baan, R A, Partensky, C, Rice, J M & Wilbourn, J D (2000) Evaluation of the carcinogenic risks to humans associated with surgical implants and other foreign bodies – a report of an IARC Monographs Programme meeting. *Eur J Cancer* **36**: 307-313

Silbergeld, E K, Waalkes, M & Rice, J M (2000) Lead as a carcinogen: Experimental evidence and mechanisms of action. *Am J Ind Med* **38**: 316-323

Jackson, M A, Stack, H F, Rice, J M & Waters, M D (2000) A review of the genetic and related effects of 1,3-butadiene in rodents and humans. *Mutat Res* **463**: 181-213

IARC (2001) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 78: Ionizing radiation, part 2: Some internally deposited radionuclides

Bird, M G, Rice, J M & Bond, J A (2001) Evaluation of 1,3-butadiene, isoprene and chloroprene health risks. *Chem Biol Interactions* **135-136**: 1-7

Rice, J M & Boffetta, P (2001) 1,3-Butadiene, isoprene and chloroprene: Reviews by the IARC Monographs programme: outstanding issues and research priorities in epidemiology. *Chem Biol Interactions* **135-136**: 11-26

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

CHECKLIST

GRANT NUMBER

CA 33193-20

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 \$ 580,000 x Rate applied 13 % = F&A costs \$ 75,400

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)