

***** NOTICE OF GRANT AWARD *****
RESEARCH PROJECT COOPERATIVE AGREEMENT Issue Date: 09/20/2004

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

Grant Number: 5 U01 CA033193-23
Principal Investigator: Cogliano, Vincent J 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: 09/01/2004 - 08/31/2005
Project Period: 09/01/1985 - 08/31/2005

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$716,197 (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,



Joy Kearse
Grants Management Officer
NATIONAL CANCER INSTITUTE

See additional information below

SECTION I - AWARD DATA - 5 U01 CA033193-23

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$335,633
Fringe Benefits	\$107,858
Personnel Costs	\$443,491
Consultant Services	\$44,477
Travel Costs	\$2,138
Other Costs	\$143,697
Federal Direct Costs	\$633,803
Federal F&A Costs	\$82,394
APPROVED BUDGET	\$716,197
TOTAL FEDERAL AWARD AMOUNT	\$716,197

FISCAL INFORMATION:

CFDA Number: 93.393

EIN: 1900210016A1

Document Number: U1CA33193E

-/ CAN / FY2004

CA/8423126 / 716,197

NIH ADMINISTRATIVE DATA:

PCC: 38CG3126 / OC: 41.4P /Processed: KEARSEJ 040917 0155

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 CA033193-23

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 CA033193-23

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 the 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:

NEW REQUIREMENT BEGINNING NOVEMBER 1, 2001: If a competing continuation application is submitted for this project, the requested budget is subject to the direct cost cap calculated in accordance with the National Cancer Institute's (NCI) policy, "Policy for Allowable Requested Budget Levels of Competing Continuation (Type 2) R01 and U01 Applications." This policy was announced in the NIH Guide for Grants and Contracts on August 7, 2001 and is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-01-016.html>.

For most awards, the last noncompeting year has the largest budget; and the competing continuation budget request cannot exceed an increase of 20% over the direct cost level of the last noncompeting year. However, in order to determine the maximum amount that you can request, it is recommended that you also read Frequently Asked Questions, which are posted on the NCI Internet at <http://deainfo.nci.nih.gov/grantspolicies/newbudgetcap-faq.htm>. It is extremely important for you to read and adhere to these guidelines. Competing continuation applications requesting increases in excess of this policy without prior approval from the NCI may be returned without review and may result in the loss of a full review cycle.

A request for a hard copy of the policy and/or questions about the policy should be directed to the NCI grants management specialist or the NCI program director identified on the award notice.

INFORMATION This award represents the final year of the competitive segment for this grant. Therefore, as stated in the NIH Grants Policy Statement, December 2003, (http://grants2.nih.gov/grants/policy/nihgps_2003/) a Financial Status Report (OMB form SF-269) (<http://grants1.nih.gov/grants/forms.htm>) must be submitted within 90 days of the expiration date. In addition, unless an application for competitive renewal is funded, grant closeout documents consisting of a Final Invention Statement (HHS form 568 available at <http://grants1.nih.gov/grants/forms.htm>), (not applicable to training, construction, conference or cancer education grants) and a Final Progress Report must also be submitted within 90 days of the expiration date.

The Final Progress Report may be typed on plain white paper and should include, at a minimum, a summary statement of progress toward the achievement of the originally stated aims, a list of results (positive or negative) considered significant, and a list of publications resulting from the project as well as plans for further publications. An original and one copy are required.

The Final Progress Report and Final Invention Statement should be sent to:

National Cancer Institute (NCI)
Records Management Center
Executive Plaza South
6120 Executive Boulevard, Room T42, MSC 7107
Bethesda, MD 20892-7107
Express Mail/Courier Service: Rockville, MD 20852
Phone: 301-496-7756
FAX: 301-496-8662

The Financial Status Report should be submitted electronically to the Office of Financial Management, NIH. Other Financial Status Reports may be mailed to:

GOVERNMENT ACCOUNTING BRANCH
OFFICE OF FINANCIAL MANAGEMENT
NATIONAL INSTITUTES OF HEALTH
31 CENTER DRIVE, ROOM B1B05A, MSC 2050
BETHESDA, MD 20892-2050

INFORMATION Your request for additional funds has not been approved. National Cancer Institute staff have determined that there is sufficient flexibility within the awarded grant budget to permit the research to proceed.

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. David Longfellow, at (301) 496-9448.

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 CA033193-23

P.I.: Cogliano, Vincent J

INSTITUTION: WORLD HLTH ORG INTL AGCY RES ON CANCER

	YEAR 23
	=====
Salaries and Wages	335,633
Fringe Benefits	107,858
Personnel Costs	443,491
Consultant Services	44,477
Travel Costs	2,138
Other Costs	143,697
TOTAL FEDERAL DC	633,803
TOTAL FEDERAL F&A	82,394
TOTAL COST	716,197

	YEAR 23
	=====
F&A Cost Rate 1	13.00%
F&A Cost Base 1	633,803
F&A Costs 1	82,394

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.



Form Approved Through 5/2004

OMB No. 0925-0001

Department of Health and Human Services
Public Health Services**Grant Progress Report****JUN 28 2004**

Review Group	Type	Activity	Grant Number
	5	U01	CA33193-23

Total Project Period	Through: 08/31/2005
From: 09/01/1985	

Requested Budget Period:	Through: 08/31/2005
From: 09/01/2004	

1. TITLE OF PROJECT

Evaluation of Carcinogenic risks to Humans

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR

(Name and address, street, city, state, zip code)

Vincent James Cogliano
Carcinogen Identification & Evaluation
International Agency for Research on Cancer
150 cours Albert Thomas
69372 Lyon Cedex 08, France

3. APPLICANT ORGANIZATION

(Name and address, street, city, state, zip code)

International Agency for Research on Cancer
150 cours Albert Thomas
69372 Lyon Cedex 08
France

2b. E-MAIL ADDRESS

cie@iarc.fr

4. ENTITY IDENTIFICATION NUMBER

1900210016A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT**5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL**

Director, Division of Administration & Finance
International Agency for Research on Cancer
150 cours Albert Thomas
69372 Lyon Cedex 08, France

2d. MAJOR SUBDIVISION

Carcinogen Identification & Evaluation

E-MAIL: daf@iarc.fr

6. HUMAN SUBJECTS
☒ No
☐ Yes

 6a. Research Exempt
☐ No ☐ Yes

6b. Human Subjects Assurance No.

 If Exempt ("Yes" in 6a):
 Exemption No.

 6c. NIH-Defined Phase III
 Clinical Trial ☐ No ☐ Yes

 If Not Exempt ("No" in 6a):
 IRB approval date

☐ Full IRB or
☐ Expedited Review
7. VERTEBRATE ANIMALS
☒ No
☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$741,000

8b. TOTAL \$837,330

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported
☐ Not Previously Reported
10. PERFORMANCE SITE(S) (Organizations and addresses)

International Agency for Research on Cancer
150 cours Albert Thomas
69372 Lyon Cedex 08
France

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)

Vincent James Cogliano

TEL +33 472 73 84 76

FAX +33 472 73 83 19

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)

Michael P Johnson

TEL +33 472 73 84 67

FAX +33 472 73 85 75

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)

NAME Peter Boyle

TITLE Director

TEL +33 472 72 86 84

FAX +33 472 73 85 75

E-MAIL director@iarc.fr

12. Corrections to Page 1 Face Page

13. 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/PPD NAMED IN 2a.
(In ink. "Per" signature not acceptable.)

DATE

26 June 2004

14. 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 Services 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 11c. (In ink. "Per" signature not acceptable.)

DATE

22/6/2004

Principal Investigator/Program Director (Last, first, middle): **COGLIANO, Vincent James**

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY		FROM 09/01/04	THROUGH 08/31/05	GRANT NUMBER CA 33193-23		
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTALS
COGLIANO, V. J.	Principal Investigator	(b)(4), (b)(6)	(b)(4), (b)(6)	-0	-0	-0
BAAN, R.	Scientist			104,200	34,700	138,900
STRAIF, K.	Scientist			99,200	33,100	132,300
SECRETAN, B.	Scientist			61,600	17,400	79,000
EL-GHISSASSI, F.	Scientist			30,800	8,700	39,500
LEZERE, M.	Publ. support			55,100	18,400	73,500
EGRAZ, S.	Archivist			41,500	13,800	55,300
SUBTOTALS				392,400	126,100	518,500
CONSULTANT COSTS						
See page 3						52,000
EQUIPMENT (Itemize)						
SUPPLIES (Itemize by category)						
TRAVEL						
One trip of the PI to USA for a scientific meeting & to consult with NCI program officials						2,500
PATIENT CARE COSTS		INPATIENT				
		OUTPATIENT				
ALTERATIONS AND RENOVATIONS (Itemize by category)						
OTHER EXPENSES (Itemize by category)						
See page 3						168,000
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD						\$741,000
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS				
		FACILITIES AND ADMINISTRATIVE COSTS				
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 9a, Face Page)						\$741,000

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

BUDGET JUSTIFICATION

GRANT NUMBER
CA 33193-23

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

CONSULTANT

- Preparation of draft monographs	
\$400/expert x 20 experts x 2 Monographs =	\$ 16,000
 - Editing of Monographs	
\$18,000 per volume x 2 volumes	\$ 36,000
	<u>\$ 52,000</u>

OTHER

- Working groups (\$45,000 x 2)	\$ 90,000
- Printing of Monographs (\$25,000 x 2)	\$ 50,000
- Distribution of free monographs (\$5,000 x 2)	\$ 10,000
- Reprint requests	\$ 8,000
- Books, journals & reproduction costs	<u>\$ 10,000</u>
	\$168,000

CURRENT BUDGET PERIOD	FROM 09/01/03	THROUGH 08/31/04
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	Total estimated expenditure	Estimated unobligated balance
	-----	-----
DIRECT COSTS	\$ 615,342	\$ 0
INDIRECT COSTS	\$ 79,994	\$ 0
TOTAL	\$ 695,336	\$ 0

Budget Justification

The funds requested from the National Cancer Institute for the continuation of the currently supported project amount to \$741,000, indirect costs excluded, for the period 1 September 2004 to 31 August 2005. The Committed Level for this period in the Notice of Grant Award dated 02/06/2004 amounts to \$633,803, after the 15% reduction applied on the Corrected Recommended Level of Support.

The budget essentially represents the cost of maintaining the ongoing programme, i.e. three meetings and three Monographs volumes per year, assuming that one working group and one volume will be financed from other sources. The number of posts to be supported by the grant is the same as in Year 22: 3.5 scientists and 2 secretarial staff.

The increase of \$107,197 above the Recommended Support relates to the following factors:

Recommended Support for Year 23		\$633,803
PLUS: Currency realignments	\$103,636 (16%)	
Cost increase	<u>\$ 3,561 (1%)</u>	
		<u>\$107,197</u>
REQUESTED BUDGET FOR YEAR 23		\$741,000

The support for Year 23 was recommended on the basis of an exchange rate of €0.954 (FF6.26) to the US dollar, compared with the rate of €0.816 used for the present application. This drop of the dollar value results in an increase of 17% of the dollar equivalent of Euro expenditure.

Principal Investigator/Program Director (Last, first, middle): Cogliano, Vincent James

Other Active Support - Dr V. J. Cogliano, Principal Investigator

(b) (4)

1/01/04 – 31/12/04
\$48,960

(b) %
(4)

The IARC Monographs 2003

No overlap with the NCI cooperative agreement. Funds used to support the 3rd Monographs meeting each year and scientific or advisory meetings relevant to the Monographs Programme.

R-82928801-1

1/06/04 – 31/05/05
\$22,100

(b) %
(4)

US Environmental Protection Agency

International Research, Evaluation and Education in Environmental Carcinogenesis

No overlap with the NCI cooperative agreement. Funds used to support the 3rd Monographs meeting each year and scientific and advisory meetings relevant to the Monographs Programme.

US National Institute of Environmental Health Sciences (no time limit)

\$79,600 in 2004

(b) %
(4)

Donation in support of the Monographs Programme, used to support the 3rd Monographs meeting each year and scientific and advisory meetings relevant to the Monographs Programme.

(Other key personnel have no active support)

Principal Investigator/Program Director (Last, first, middle): **COGLIANO, Vincent James**

PROGRESS REPORT SUMMARY

GRANT NUMBER
CA33193-22

PERIOD COVERED BY THIS REPORT

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
COGLIANO, Vincent James

FROM
09/01/2003

THROUGH
08/31/2004

APPLICANT ORGANIZATION

International Agency for Research on Cancer

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)

Evaluation of Carcinogenic Risks to Humans

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Has there been a change in the other support of key personnel since the last reporting period? No.

Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project? None anticipated.

Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget? No.

a. **Specific Aims.** The *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* critically reviews and evaluates the published scientific evidence on carcinogenic hazards to which humans are exposed. These include chemicals, complex mixtures, occupational exposures, lifestyle factors, and physical and biological agents. International, interdisciplinary working groups of expert scientists prepare the critical reviews and consensus evaluations.

b. **Studies and Results.** During the past reporting year, IARC convened three separate working groups on different agents or exposures suspected of causing cancer in humans. [NCI funding supported two of these working groups.] The topics were selected from the list of high priorities for future evaluations recommended by an *IARC Monographs* Advisory Group in February 2003.

Volume 86: Cobalt in hard-metals and cobalt sulfate, gallium arsenide, indium phosphide and vanadium pentoxide. New cancer studies have become available for several metal compounds to which workers in the hard-metal industry are exposed. A working group of 17 scientists from 10 countries met in October 2003 to develop the following evaluations.

Cobalt metal with tungsten carbide	2A	<i>Probably carcinogenic to humans</i>
Cobalt metal w/o tungsten carbide	2B	<i>Possibly carcinogenic to humans</i>
Cobalt sulfate	2B	<i>Possibly carcinogenic to humans</i>
Soluble cobalt (II) salts	2B	<i>Possibly carcinogenic to humans</i>
Gallium arsenide	1	<i>Carcinogenic to humans</i>
Indium phosphide	2A	<i>Probably carcinogenic to humans</i>
Vanadium pentoxide	2B	<i>Possibly carcinogenic to humans</i>

Volume 87: Inorganic and organic lead compounds. All humans carry a body burden of lead. The predominant use of lead is now in batteries and, to a lesser extent, in construction materials and lead-based chemicals. A working group of 20 scientists from 11 countries met in February

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James
2004 to develop the following evaluations.

Inorganic lead compounds	2A	<i>Probably carcinogenic to humans</i>
Organic lead compounds	3	<i>Not classifiable</i>

Volume 88: Formaldehyde, 2-butoxyethanol and 1-tert-butoxy-2-propanol. New cancer studies and mechanistic information have become available for formaldehyde and some glycol ethers, compounds to which human exposure is widespread. A working group of 26 scientists from 10 countries met in June 2004 to develop the following evaluations.

Formaldehyde	1	<i>Carcinogenic to humans</i>
2-Butoxyethanol	3	<i>Not classifiable</i>
1-tert-Butoxy-2-propanol	3	<i>Not classifiable</i>

IARC also completed and distributed volume 83 (*Tobacco smoke and involuntary smoking*). The next several volumes (84-86) are being readied for printing and distribution during 2004.

In addition, a scientific workshop was held in November 2003 to develop a joint IARC/WHO/FAO report on *Management of mycotoxins in food and feeds*. This effort arose out of the *IARC Monograph* on mycotoxins (volume 82). [This workshop and publication do not use NCI funds, but are mentioned for completeness in reporting overall progress.]

c. Significance. Nearly 400 potentially carcinogenic agents and exposures have been identified in the 88 volumes and approximately 900 evaluations developed to date. National and international health agencies use the *IARC Monographs* as an authoritative source of scientific information and as the scientific basis for their efforts to control cancer. The *IARC Monographs* are also a resource to the scientific community for other information on agents suspected of causing cancer.

d. Plans. During the period from September 2004 through August 2005, IARC will convene three expert working groups to evaluate information on high-priority potentially carcinogenic agents. [NCI funding will support two of these working groups.]

Volume 89: Smokeless tobacco and some related nitrosamines. A working group tentatively consisting of 18 scientists from 7 countries will meet in October 2004 to develop evaluations of smokeless tobacco and five nitrosamines: NNAL, NNK, NAB, NAT, and NNN.

Volume 90: Human papilloma viruses. A working group will meet in February 2005 to evaluate the new evidence of carcinogenicity for human papilloma viruses. The specific viral agents to be evaluated will be determined by the working group, which is being selected as this progress report is being prepared.

Volume 91. The last working group during the project period will meet in June 2005. The topic and expert members will be selected by August 2004.

Additionally, a scientific workshop is being planned to obtain scientific advice on potential revisions of the *Preamble to the IARC Monographs*. [This meeting will not use NCI funds, but is mentioned for completeness in describing overall plans for the next reporting period.]

e. Publications

IARC (2004) Tobacco smoke and involuntary smoking. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol 83. Lyon: IARC Press.

IARC (in preparation) Some drinking-water disinfectants and contaminants, including arsenic. *IARC*

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

Monographs on the Evaluation of Carcinogenic Risks to Humans, vol 84.

IARC (in preparation) Betel-quid and areca-nut chewing and some related nitrosamines. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol 85.

IARC (in preparation) Cobalt in hard-metals and cobalt sulfate, gallium arsenide, indium phosphide and vanadium pentoxide. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol 86.

IARC (in preparation) Inorganic and organic lead compounds. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol 87.

IARC (in preparation) Formaldehyde, 2-butoxyethanol and 1-tert-butoxy-2-propanol. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol 88.

f. Project-Generated Resources. None.

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

GRANT NUMBER
CA 33193-23

CHECKLIST

1. PROGRAM INCOME (See instructions.)

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)

2. ASSURANCES/CERTIFICATIONS (See instructions.)

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. Descriptions of individual assurances/certifications are provided in Section III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects •Research Using Human Embryonic Stem Cells •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy •Vertebrate Animals

•Debarment and Suspension •Drug-Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only); •Lobbying •Non-Delinquency on 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 HHS 690); •Recombinant DNA and Human Gene Transfer Research •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINISTRATIVE (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. If F&A costs will not be paid on 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, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☐ DHHS Agreement dated: _____ ☐ No Facilities and Administrative Costs Requested.

☒ No DHHS Agreement, but rate established with J. W. Berry, Accountant, DHHS Date 18/10/1983

CALCULATION*

Entire proposed budget period: Amount of base \$ 741,000 x Rate applied 13.00 % = F&A costs \$ 96,330

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☒ Other base (Explain)
☐ Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.): Rate applied to total direct costs

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

PERSONNEL REPORT

GRANT NUMBER
CA33193-23

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

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
VJ Cogliano	PhD	(b)(6)	PI	(b)(6)	(b)(4), (b)(6)
R Baan	PhD	-	Scientist		
F ElGhissassi	PhD	-	Scientist		
Y Grosse	PhD	-	Scientist		
B Secretan	PhD	-	Scientist		
K Straif	PhD	-	Scientist		