

to assure that unwarranted duplication of federally-funded research does not occur. The secondary review committee has the latitude to recommend to the NCIPC Director, to reach over better-ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010," the Institute of Medicine report, "Reducing the Burden of Injury," and the "CDC Injury Research Agenda."

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the IRG, recommendations by the secondary review committee, ACIPC, consultation with NCIPC senior staff, and the availability of funds.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

VI. Award Administration Information

VI.1. Award Notices: Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

2. Administrative and National Policy Requirements: 45 CFR part 74 and part 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements

- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

- AR-14 Accounting System Requirements

- AR-15 Proof of Non-Profit Status
- AR-16 Security Clearance

Requirement

- AR-21 Small, Minority, and Women-Owned Business
- AR-22 Research Integrity
- AR-23 States and Faith-Based Organizations

- AR-24 Health Insurance Portability and Accountability Act Requirements

- AR-25 Release and Sharing of Data

Starting with the December 1, 2003 receipt date, all NCIPC funded investigators seeking more than \$250,000 in total costs in a single year are expected to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing/release, including the timeliness and name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing/release may also be appropriate in other sections of the application (e.g. background and significance, human subjects requirements, etc.). The content of the data sharing/release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing/release plan will not count towards the application page limit and will not factor into the determination scientific merit or priority scores. Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or visiting the NCIPC Internet Web site at: http://www.cdc.gov/ncipc/osp/sharing_policy.htm.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting: You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925-0001, rev. 5/2001) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For scientific/research program technical assistance, contact: Jennifer Wyatt, Behavioral Scientist, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K-60, Atlanta, Georgia 30341, Telephone: 770-488-4058, E-mail: ANU1@cdc.gov.

For questions about peer review, contact: Gwendolyn Cattledge, Scientific Review Administrator, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K-02, Atlanta, Georgia 30341, Telephone: 770-488-1430, E-mail: gxc8@cdc.gov.

For budget assistance, contact:

Nancy Pillar, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2721, E-mail: nfp6@cdc.gov.

Dated: November 25, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E-0253]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEXAPRO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined