

C. Determine and manage all promotional activities (e.g., title, logo, announcements, mailers, press releases, etc.). ATSDR must review and approve all materials with reference to ATSDR involvement or support.

D. Manage all registrants (e.g., travel, reservations, correspondence, conference materials and hand-outs, badges, registration procedures, etc.).

E. Plan, negotiate, and manage conference site arrangements, including all audio-visual needs.

F. Develop and conduct education and training programs on prevention of health effects of hazardous substances.

G. Participate in the analysis of data from conference activities.

H. Collaborate with ATSDR staff in reporting and disseminating results and relevant prevention education and training information to appropriate Federal, State, and local agencies, and the general public.

Evaluation Criteria

Applications for support of the types of conferences listed in the Purpose section above will be reviewed and evaluated according to the following criteria:

A. Proposed Program and Technical Approach—50%

The description of: (a) the public health significance of the proposed conference including the degree to which the conference can be expected to influence the prevention of exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases and other sources of pollution present in the environment; (b) the feasibility of the conference in terms of an operational plan; (c) clearly stated conference objectives and the potential for accomplishing those objectives; and (d) the method of evaluating the conference.

B. The Qualification of Program Personnel—30%

Evaluation will be based on the extent to which the proposal has described: (a) the qualifications, experience, and commitment of the principal staff person, and his/her ability to devote adequate time and effort to provide effective leadership, and (b) the competence of associate staff persons, discussion leaders, speakers, and presenters to accomplish the proposed conference.

C. Applicant Capability—20%

Evaluation will be based on the description of (a) the adequacy and

commitment of institutional resources to administer the program, and (b) the adequacy of the facilities to be used for the conference.

D. Budget Justification and Adequacy of Facilities (Not Scored)

The proposed budget will be evaluated on the basis of its reasonableness, concise and clear justification, and consistency with the intended use of grant funds. Applications requesting funds in excess of \$30,000 may not be fully funded, depending upon availability of funds. The application will also be reviewed as to the adequacy of existing and proposed facilities and resources for conducting conference activities.

Executive Order 12372 Review

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number is 93.161.

Application Submission and Deadline

The original and two copies of the Application Form PHS 5161-1 (OMB Number 0937-0189) shall be submitted to Henry S. Cassell, III, Grants Management Branch, Procurement and Grants Office, 255 East Paces Ferry Rd., NE., Room 300, Mailstop E-13, Atlanta, GA 30305, on or before June 13, 1995. By formal agreement, the CDC Procurement and Grants Office will act on behalf of and for ATSDR on this matter.

1. Deadline

Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the review committee. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications

Applications that do not meet the criteria in 1.a. or 1.b. above are considered late applications and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 516. You will receive a complete program description, information on application procedures and application forms.

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from Margaret A. Slay, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, telephone (404) 842-6797. Programmatic technical assistance may be obtained from Diana Cronin, Project Officer, Agency for Toxic Substances and Disease Registry, Division of Health Education, 1600 Clifton Road, NE., Mailstop E-33, Atlanta, GA 30333, telephone (404) 639-6206.

Please refer to Announcement 516 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: April 4, 1995.

David Satcher,

Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 95-8716 Filed 4-7-95; 8:45 am]

BILLING CODE 4163-70-P

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry Policy on the Inclusion of Women and Minorities in Externally Awarded Research

AGENCY: Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service (PHS), Department of Health and Human Services (DHHS).

ACTION: Notice and request for comments.

SUMMARY: This notice is a request for comments on the CDC¹ policy on the inclusion of women and minorities in externally awarded research. This policy is intended to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC supported studies involving human subjects, whenever feasible and appropriate. Furthermore, it is CDC policy to proactively identify significant gaps in knowledge about health problems that affect women and racial and ethnic minority populations and to encourage studies which address these problems. (NOTE: This policy is consistent with requirements for CDC intraagency research.)

DATES: Written comments on the policy must be received on or before June 9, 1995. This policy, when finalized, will be applicable for all CDC externally awarded projects submitted on and after October 1, 1995.

ADDRESSES: Written comments can be sent to the Centers for Disease Control and Prevention, Attention: Office of the Associate Director for Science, Mailstop D-39, 1600 Clifton Road, NE., Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT: Inquiries should be directed to Dixie E. Snider, Jr., M.D., M.P.H., telephone (404) 639-3701 or Barbara W. Kilbourne, R.N., M.P.H., telephone (404) 639-1242.

SUPPLEMENTARY INFORMATION: CDC Policy on the Inclusion of Women and Minorities in Externally Awarded Research.

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CDC Inclusion Review Committee
Responsibility and Members

I. Introduction

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) are committed to protecting the health of all people regardless of their sex, race, ethnicity, national origin, religion, sexual orientation, socioeconomic status, or other characteristics. To the extent that participation in research offers direct benefits to the participants, underrepresentation of certain population subgroups denies them the opportunity to benefit. Moreover, for purposes of generalizing study results, investigators must include the widest possible range of population groups.

A growing body of evidence indicates that the health conditions and needs of women are different from those of men. Some health conditions are unique to women and others are more prevalent in women. For some illnesses, there are marked distinctions, not only in onset and progression of disease, but also in the preventive, treatment and educational approaches necessary to combat them in women. Furthermore, initial entry into the health care system may be different for some subgroups of women, such as poor and uninsured women. Lesbians may also enter the health care system differently because they may be less likely to seek or receive prevention services, like cancer screening, because they may not seek or receive family planning services. The Public Health Service Task Force on Women's Health Issues published a report in 1987 stating that it is becoming more important to note the environmental, economic, social, and demographic characteristics that influence a woman's health status. The Task Force focused in on the direct and indirect effects these factors could have on the status of a woman's health and noted that when a woman is "outside the normal range of societal expectations," that is, she is of an ethnic or cultural minority or if she is physically or mentally disabled, her health status is at greater risk. These basic observations are not always recognized or reflected in study protocols and proposals.

The disparity in health outcomes between majority and some racial and ethnic minority groups is now well documented. Although some minority populations, e.g., some Asian groups, have better overall health status than non-Hispanic whites, many racial and ethnic minority populations have dramatically shorter life expectancy,

higher morbidity rates and inadequate access to quality health care. The Secretary's Task Force on Black and Minority Health issued a report in 1985 noting the underrepresentation of racial and ethnic minorities in research. This underrepresentation has resulted in significant gaps in knowledge about the health of racial and ethnic minority populations and their responses to interventions.

II. Definitions

A. Human Subjects

Under this policy, the definition of human subjects in Title 45 CFR Part 46, the Department of Health and Human Services regulations for the protection of human subjects applies: "Human subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

B. Research

Under this policy, the definition of research in Title 45 CFR Part 46, the Department of Health and Human Services regulations for the protection of human subjects applies: "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." All proposed research involving human subjects conducted using CDC funding will be evaluated for compliance with this policy, including those projects that are exempt from Institutional Review Board (IRB) Review (as specified in Title 45 CFR Part 46). However, nothing in this policy is intended to require IRB review of protocols which otherwise would be exempt. This policy applies to all CDC externally awarded research regardless of the mechanism of financial support (e.g., grant, cooperative agreement, contract, purchase order, etc.). This policy does not apply to those projects in which the investigator has no control over the composition of the study population (e.g., cohort studies in which the population has been previously selected or research follow-up to outbreak investigations).

C. Racial and Ethnic Categories

1. Minority Groups

This policy shall comply with the Office of Management and Budget (OMB) Directive No. 15 and any changes that may occur as it is reviewed and revised. OMB Directive No. 15 defines the minimum standard of basic racial and ethnic categories, which are used below. Despite their limitations (as

¹ References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

outlined in the Public Health Reports "Papers from the CDC/ATSDR Workshop on the Use of Race and Ethnicity in Public Health Surveillance"), these categories are useful because they allow comparisons to many national data bases, especially Bureau of the Census and national health data bases. Therefore, the racial and ethnic categories described below should be used as basic minimum guidance, cognizant of their limitations.

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

2. Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

While investigators should focus primary attention on the above categories, CDC recognizes the diversity of the population. For example, Blacks describe themselves in several different ways: African American and Caribbean (Haitian, Jamaican, West Indian, Trinidadian). Native Hawaiians have expressed the desire to be considered a separate racial/ethnic category exclusive of the current Asian/Pacific Islander designation. Therefore, investigators are encouraged to investigate national or geographic origin or other cultural factors (e.g., customs, beliefs, religious practices, etc.) in studies of race and ethnicity, and their relationship to health problems. Furthermore, since race, ethnicity, and cultural heritage may serve as markers for other important characteristics or conditions associated with a health problem or outcome, investigators should actively seek to identify these other characteristics or conditions.

III. Policy

Research Involving Human Subjects

Applicant institutions must ensure that women and racial and ethnic

minority populations are appropriately represented in their proposals for research. Women and members of racial and ethnic minority groups should be adequately represented in all CDC-supported studies involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the CDC that inclusion is inappropriate or clearly not feasible. This policy does not apply to studies when the investigator cannot control the race, ethnicity, and sex of subjects; however, women and racial and ethnic minority populations must not be routinely and/or arbitrarily excluded from such investigations. Women of childbearing potential should also not be routinely and/or arbitrarily excluded from participation; however, there are ethical/risk issues to consider for exclusion. Information on differences in outcome or risk profiles should be further reason for exclusion. Therefore, pregnancy status may need to be determined prior to enrollment for some studies and, if necessary, during an intervention to safeguard the participants' health.

IV. Guidance for Applicant Institution Investigators and Decision Makers in Complying With This Policy

A General

In determining whether special efforts should be made to set specific enrollment goals for women and members of racial and ethnic minority groups in research or whether to design special studies to specifically address health problems in such populations, principal investigators should consider the following points:

- Is the disease or condition under study unique to, or is it relatively rare in men, women or one or more racial and ethnic minority populations?
- What are the characteristics of the population to which the protocol results will be applied? Does it include both men and women? Does it include specific racial and ethnic minority populations?
 - Are there scientific reasons to anticipate significant differences between men and women and among racial and ethnic minority populations with regard to the hypothesis under investigation?
 - Are there study design or recruitment limitations in the protocol that could result, unnecessarily, in underrepresentation of one sex or certain racial and ethnic minority populations?
 - Could such underrepresentation cause an adverse impact on the

generalizability and application of results?

- Is the underrepresentation correctable?
- Does racial and ethnic characterization of study subjects serve a *bona fide* purpose or might it serve only to stigmatize a group?

Inclusion of women and/or racial and ethnic minority groups in research can be addressed either by including all appropriate groups in one single study or by conducting multiple studies. In general, protocols and proposals for support of studies involving human subjects should employ a design with sex and/or minority representation appropriate to the scientific objectives. It is not an automatic requirement that the study design provide sufficient statistical power to answer the questions posed for men and women and racial and ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women and/or racial and ethnic groups, with regard to the hypothesis under investigation, investigators should include an evaluation of these sex and minority group differences in the study proposal. If adequate inclusion of one sex and/or minority group is impossible or inappropriate with respect to the purpose of the proposed study, or if in the only study population available, there is a disproportionate representation of one sex or minority/majority group, the rationale for the study population must be well explained and justified. The cost of inclusion of women and/or racial and ethnic minority groups shall not be a permissible consideration for exclusion from a given study unless data regarding women and/or racial and ethnic minority groups have been or will be obtained through other means that provide data of comparable quality. Acceptable reasons for exclusion are as follows:

- (1) Inclusion is inappropriate with respect to the health of the subjects;
 - (2) Inclusion is inappropriate with respect to the purpose of the study;
 - (3) There is substantial scientific evidence that there is no significant difference between the effects that the variables to be studied have on women and/or racial and ethnic minority groups;
 - (4) There are already substantial scientific data on the effects that variables have on the excluded population;
 - (5) Inclusion is inappropriate under other circumstances determined acceptable by the CDC.
- In each protocol or proposal, the composition of the proposed study

population must be described in terms of sex and racial and ethnic group together with a rationale for its choices. Sex and racial and ethnic issues should be addressed in developing a study design and sample size appropriate for the scientific objectives of the investigation. The proposal should contain a description of the proposed outreach programs, if necessary, for recruiting women and racial and ethnic minorities as participants. Investigators must safeguard the consent process by promoting open and free communication with the study participants. Investigators must seek to understand cultural differences and variety of languages inherent in the population to be enrolled. The possibility of non-proficiency of speaking and/or reading English by a potential study participant must be considered and assurances given that adequate provision has been made for appropriate translation of the consent document or the availability of translators to ensure an adequate understanding of the research.

B. Studies of Public Health Interventions

Investigators must consider the following when planning an intervention trial:

- If the data from prior studies strongly indicate the existence of significant differences of clinical or public health importance in intervention effect between the sexes or among racial and ethnic populations, the primary question(s) to be addressed by the scientific investigation and the design of that study must specifically accommodate this. For example, if men, women, and racial and ethnic minority groups are thought to respond differently to an intervention, then the study should be designed to answer separate primary questions that apply to men, women, and/or specific racial and ethnic groups with adequate sample size for each.

- If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect between subgroups, then sex and race and ethnicity are not required as subject selection criteria. However, the inclusion of sex and racial and ethnic subgroups is still strongly encouraged.

- If the data from prior studies neither support nor negate the existence of significant differences of clinical or public health importance in intervention effect, then the study should include sufficient and appropriate entry of men and women and racial and ethnic minority populations so that valid analysis of the

intervention effect in each subgroup can be performed.

- If women of childbearing potential are to be included and if there is a reason to suspect that there may be adverse events in pregnant women, pregnancy status may need to be determined prior to enrollment for some intervention trials.

V. Implementation

A. Date of Implementation

This policy applies to all CDC externally awarded projects submitted on and after October 1, 1995.

B. Roles and Responsibilities

Certain individuals and groups have special roles and responsibilities with regard to the implementation of these guidelines.

1. Applicant Institution Investigators

Applicant institution investigators should assess the theoretical and/or scientific linkages between sex and race and ethnicity and their topic of study. Following this assessment, the applicant institution investigator will address the policy in each protocol, application and proposal, providing the required information on inclusion of women and minorities in studies, and any required justifications for exceptions to the policy.

2. CDC Technical/Peer Review Groups

In conducting technical/peer review of contract, grant, or cooperative agreement applications for scientific and technical merit, CDC Center/Institute/Office (C/I/O) Directors will ensure that CDC technical/peer review groups, to the extent possible, should include women and racial and ethnic minorities and will do the following:*

- Evaluate the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation or evaluate the proposed justification when representation is limited or absent.
- Evaluate the proposed exclusion of a certain racial and ethnic minority population and males or females on the basis that a requirement for inclusion is inappropriate.

*C/I/O Directors may waive this requirement if it is clearly inappropriate or clearly not feasible.

- Determine whether the design of the study is adequate to measure differences when warranted.
- Evaluate the plans for recruitment and outreach for study participants including whether the process of establishing partnerships with community(ies) and recognition of mutual benefits will be documented.

- Include these criteria as part of the technical assessment and assign a score.

3. CDC Center/Institute/Office Directors

CDC C/I/O Directors are responsible for ensuring that CDC externally awarded research involving human subjects meet the requirements of these guidelines. CDC C/I/O Directors will also inform externally awarded investigators concerning this policy and monitor its implementation during the development, review, award, and conduct of research.

4. CDC Institutional Review Boards (IRBs)

CDC IRBs are responsible for ensuring that CDC investigators have adequately addressed the inclusion of women and racial and ethnic minorities in research protocols that require CDC IRB approval.

C. External Award Consideration

CDC project officers shall design their Requests for Contracts and Requests for Assistance in compliance with this policy. CDC C/I/O Directors shall ensure this policy is fully considered and implemented prior to the release of the Request for Contract and Request for Assistance to the CDC Procurement and Grants Office. CDC funding components will not award any grant, cooperative agreement, or contract nor support any externally funded project to be conducted or funded in fiscal year 1996 and thereafter which does not comply with this policy.

D. Recruitment Outreach by Externally Awarded Investigators

Externally awarded investigators and their staff(s) are urged to develop appropriate and culturally sensitive outreach programs and activities commensurate with the goals of the research. The purpose should be to establish a relationship between the investigator(s), populations, and community(ies) of interest so that mutual benefit is achieved by all groups participating in the study. Investigators should document the process for establishing a partnership with the community(ies) and the mutual benefits of the study and ensure that any factors (e.g., educational level, nonproficiency in English, low socioeconomic status) are accounted for and handled appropriately. In addition, investigator(s) and staff(s) should take precautionary measures to ensure that ethical concerns are clearly noted, such that there is minimal possibility of coercion or undue influence in the incentives or rewards offered in

recruiting into or retaining participants in scientific studies.

E. Dissemination of Research Results

Externally awarded investigators are urged to make special efforts to disseminate relevant research results to the communities who participated in the studies and to the populations to which they pertain, especially racial and ethnic minority populations which may have cultural, language, and socioeconomic barriers to the easy receipt of such information.

VI. Evaluation

CDC Inclusion Review Committee Responsibility and Members

A CDC Inclusion Review Committee (IRC) with representatives from the CDC Office of the Associate Director for Science, the CDC Office of the Associate Director for Minority Health, and the CDC Office of the Associate Director for Women's Health will review any questions, issues, or comments pertaining to this policy and recommend necessary changes or modifications to the Director, CDC. This committee will meet regularly to review compliance with this policy and evaluate the impact of this policy on research activities at CDC. The CDC IRC may periodically conduct random audits of research protocols to assess compliance with this policy.

Dated: March 30, 1995.

Claire V. Broome,

Deputy Director, Centers for Disease Control and Prevention (CDC) and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).

[FR Doc. 95-8718 Filed 4-7-95; 8:45 am]

BILLING CODE 4163-18-P

[Announcement 525]

Continuation of the Development of Technology for the Measurement of Lead in Blood; Notice of Availability of Funds for Fiscal Year 1995

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a grant program for the continuation of the development of new and innovative technology, or significant improvement of existing technology, for the measurement of lead in blood. CDC has supported such development efforts under a grant program since FY 1992 and under Cooperative Research and Development Agreements (CRADAs) since 1991. State, community and physician office-based childhood lead poisoning

prevention programs have a need for reasonably priced, accurate, precise, portable, rugged, and easy-to-operate instruments or analytical techniques to measure the concentration of lead in blood. Such programs screen large numbers of infants and young children and identify those with lead poisoning.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of "Healthy People 2000," see the section **Where To Obtain Additional Information.**)

Authority

This program is authorized under sections 301(a) [42 U.S.C. 241(a)] and 317B(b) [42 U.S.C. 247b-3(b)] of the Public Health Service Act, as amended.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are limited to those organizations which are currently developing innovative technology for the measurement of lead in blood, funded under CDC grant Announcement 269 (included in the application package), or organizations which have a current CDC Cooperative Research and Development Agreement (CRADA) dealing with blood lead measurement technology. However, if funded, the CDC CRADA dealing with blood lead will be terminated.

Note: Eligible applicants are encouraged to enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application.

Availability of Funds

Approximately \$800,000 is available in FY 1995 to fund up to three grants. It is expected that the average award will be \$250,000, ranging from \$100,000 to \$500,000. It is expected that the awards will begin on or about June 30, 1995, and will be made for a 12-month budget period within a project period of

up to one year. Funding estimates may vary and are subject to change.

Purpose

State and community health agencies are the principal delivery points for childhood lead screening and related medical and environmental management activities. Universal screening of children is recommended in "Preventing Lead Poisoning in Young Children—a Statement by the Centers for Disease Control," (October 1991); however, the lack of analytical systems (methods plus instrumentation) which are easy-to-operate, rugged, and suitable for field use in screening programs have made it difficult and costly for agencies to develop programs for the elimination of this totally preventable disease. This program will provide financial support for the continuation and possible completion of the development and validation of new and innovative technology leading to better blood lead measurement systems.

Program Requirements

The following are essential requirements of the Grantee:

1. Provide a principal investigator with the authority, responsibility, and research experience to carry out the objectives of the grant.
2. Provide qualified staff, laboratory and/or production facilities, equipment, and other resources necessary to carry out the objectives of the grant.
3. Conduct a scientifically sound, goal-oriented research and development program which will yield all or portions of practical analytical systems which measure one or more chemicals in complex solutions. Understand and address the difficult analytical problem presented by a blood sample matrix.
4. Publish the results of the research effort in the peer-reviewed scientific literature, or otherwise make the research findings available for objective evaluation and use.
5. Provide evidence of significant progress under the previous grant or CRADA for blood lead measurement technology consistent with the goals and objectives of the original grant or CRADA, and clearly show that successful completion could be reasonably expected within the one year project period.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Understanding of the Problem (30%)

By progress under previous grant or CRADA agreement, the Applicant has