DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3′-UTR of Dengue Types 1,2,3, And 4

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the following invention as embodied in the following patent applications: (1) E–120–2001, Whitehead *et al.,* ''Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses'', U.S. Provisional Patent Application 60/293,049, filed May 22, 2001, PCT/US02/16308, filed May 22, 2002, U.S. Patent Application 10/719,547, filed November 21, 2003, European Patent Application 02739358.6, filed May 22, 2002, Canadian Patent Application 2448329, filed May 22, 2002, Indian Patent Application 2814DELNP2003, filed May 22, 2002, Australian Patent Application 2002312011, filed May 22, 2002, and Brazilian Patent Application PI0209943.8, filed May 22, 2002, and (2) E–089–2002, ''Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3′-UTR of Dengue Types 1,2,3, And 4, or Antigenic Chimeric Dengue Viruses 1,2,3, And 4'', U.S. Provisional Applications 60/377,860, filed May 3, 2002, 60/436,500, filed December 23, 2002, PCT/US03/13279, filed April 25, 2003 to MacroGenics, Inc., having a place of business in Rockville, Maryland. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before June 7, 2004, will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *ps193c@nih.gov*; Telephone: (301) 435–4646; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The global prevalence of dengue has grown dramatically in recent decades. The disease is now endemic in more than 100 countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Southeast Asia and the Western Pacific are most seriously affected. Before 1970 only nine countries had experienced Dengue Hemorrhagic Fever (DHF) epidemics, a number that had increased more than four-fold by 1995. WHO currently estimates there may be 50 million cases of dengue infection worldwide every year.

The methods and compositions of this invention provide a means for prevention of dengue infection and dengue hemorrhagic fever (DHF) by immunization with attenuated, immunogenic viral vaccines against dengue. The vaccine is further described in Blaney JE *et al.,* ''Mutations which enhance the replication of dengue virus type 4 and an antigenic chimeric dengue virus type 2/4 vaccine candidate in Vero cells.'' *Vaccine* 2003 Oct 1;21(27–30):4317–27 and Whitehead SS *et al.,* ''A live, attenuated dengue virus type 1 vaccine candidate with a 30-nucleotide deletion in the 3′ untranslated region is highly attenuated and immunogenic in monkeys.'' *J. Virol.* 2003 Jan;77(2):1653–7.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to live attenuated vaccines against dengue infections in humans. The Licensed Territory may be limited to the United States, the European Union, Japan, and Canada.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 31, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–7926 Filed 4–7–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Request for Applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004)

Authority: Section 506B of the Public Health Service Act.

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of request for applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004).

SUMMARY: The United States Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) is accepting applications for fiscal year (FY) 2004 Cooperative Agreements for Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04–004). These cooperative agreements will expand and strengthen effective, culturally appropriate ecstasy and other club drugs prevention services at the State and local levels. The services implemented through these grants must incorporate the best objective information available regarding effectiveness and acceptability. SAMHSA/CSAP expects that the services funded through these grants will be sustained by the grantee beyond the term of the grant.

DATES: Applications are due on June 18, 2004.

FOR FURTHER INFORMATION CONTACT: For questions on program issues, contact: Tom DeLoe, Ph.D., SAMHSA/CSAP, 5600 Fishers Lane, Rockwall II, Suite 1075, Rockville, MD 20857, 301–443–9110, E-mail: *tdeloe@samhsa.gov.*

For questions on grants management issues, contact: Edna Frazier, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857, (301) 443–6816, *efrazier@samhsa.gov.*

SUPPLEMENTARY INFORMATION:

Cooperative Agreement for Ecstasy and Other Club Drugs Prevention Services (Short Title: Ecstasy and Other Club Drugs Cooperative Agreements), SP 04–004 (Initial Announcement), Catalogue of Federal Domestic Assistance (CFDA) No.: 93.243

KEY DATES

Application Deadline	Applications must be submitted by June 18, 2004.
Intergovernmental Review (E.O. 12372)	Letters from State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination.	Applicants must send the PHSIS to appropriate State and local health agencies by application deadline. Comments from Single State Agency are due no later than 60 days after application deadline.

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I. Funding Opportunity Description

1. Introduction and Background

As authorized by Section 506B of the Public Health Service Act, the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) announces the availability of funds for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services. These grants will expand and strengthen effective, culturally appropriate ecstasy and other club drugs prevention services at the State and local levels. The services implemented through these grants must incorporate the best objective information available regarding effectiveness and acceptability. SAMHSA/CSAP expects that the services funded through these grants will be sustained by the grantee beyond the term of the grant.

Ecstasy and Other Club Drugs are substances whose use can lead to serious health and behavioral problems, including memory loss, aggression, violence, psychotic behavior, and potential heart and/or neurological damage. Their use also contributes to increased transmission of infectious diseases, especially hepatitis and HIV/AIDS. Use is increasing among the general adolescent population as well as the following populations: men who have sex with men and use other drugs; young adults who attend ''raves'' or private clubs; homeless and runaway youth; and male and female commercial sex workers.

2. Expectations

The Ecstasy and Other Club Drugs Cooperative Agreements program are one of SAMHSA/CSAP's Services Grants programs. Grantees must use the funds to expand and strengthen effective, culturally appropriate Ecstasy and Other Club Drugs prevention services at the State and local levels, and SAMHSA/CSAP expects that the services will be sustained beyond the term of the grant.

SAMHSA/CSAP intends that its Services Grants, including the Ecstasy and Other Club Drugs Cooperative Agreements, will result in the delivery of services as soon as possible and encourages grantees to begin service delivery within 4 months of receiving the grant award. However, SAMHSA/CSAP recognizes that grantees may need to enhance their prevention system infrastructure in order to enhance/expand Ecstasy and Other Club Drugs prevention services. Therefore, grantees may propose an infrastructure development phase in year one of their grant projects. If a community is ready to provide services at the time of the award, service delivery may be implemented without this planning phase.

These Ecstasy and Other Drugs Cooperative Agreements will be implemented over a project period of up to five years. During this same time period, SAMHSA/CSAP will be working with the States to conduct comprehensive needs assessments in order to develop strategic plans to prevent/reduce the use of alcohol, tobacco and other drugs through a new SAMHSA/CSAP initiative called the Strategic Prevention Framework (SPF). SAMHSA/CSAP recognizes that Ecstasy and Other Drugs Cooperative Agreements grantees may need to adjust their plans as their SPF plans unfold. Therefore, amendments to the Ecstasy and Other Drugs Cooperative Agreements may be made in Years 3, 4 or 5 in order to bring the Ecstasy and Other Drugs Cooperative Agreements project into alignment with the SPF plans.

2.1 Documenting the Evidence-Base for Services To Be Implemented

The services implemented through the Ecstasy and Other Club Drugs Cooperative Agreements must incorporate the best objective information available regarding the effectiveness and acceptability of the services to be implemented. In general, the services implemented through the Ecstasy and Other Club Drugs Cooperative Agreements must have strong evidence of effectiveness. However, because the evidence base for Ecstasy and Other Club Drugs prevention is limited, SAMHSA/CSAP may fund services for which the evidence of effectiveness is based on formal consensus among recognized experts in the field and/or evaluation studies that have not been published in the peer reviewed literature.

Applicants must document in their applications that the services/practices they propose to implement are evidence-based services/practices. In addition, applicants must justify use of the proposed services/practices for the target population along with any adaptations or modifications necessary to meet the unique needs of the target population or otherwise increase the likelihood of achieving positive outcomes. Further guidance on each of these requirements is provided below.

Documenting the Evidence-Based Practice/Service

SAMHSA/CSAP has already determined that certain services/practices are solidly evidence-based services/practices. These include practices in SAMHSA/CSAP's National Registry of Effective Programs (NREP), and SAMHSA/CSAP encourages applicants to select services/practices from NREP.

None of the models listed in NREP specifically addresses prevention of Ecstasy and Other Club Drug use. However, many of the NREP models do address similar risk and protective factors associated with the prevention of Ecstasy and Other Club Drug use. SAMHSA/CSAP encourages applicants to adapt/replicate a NREP model that is culturally and developmentally appropriate for the target population to be served. To review the NREP models, go to *http://www.modelprograms.samhsa.gov/template.cfm.*

Applicants may propose other services/practices not listed in NREP, but the applicant must demonstrate evidence of effectiveness in order to receive funding. Such applicants must provide a narrative justification that summarizes the evidence for effectiveness and acceptability of the proposed service/practice. The preferred evidence of effectiveness and acceptability will include the findings from clinical trials, efficacy and/or effectiveness studies published in the peer-reviewed literature.

If little or no research specific to the proposed target population or service delivery setting has been published in the peer-reviewed scientific literature, applicants may present evidence involving studies that have not been published in the peer-reviewed research literature and/or documents describing formal consensus among recognized experts. If consensus documents are presented, they must describe consensus among multiple experts whose work is recognized and respected by others in the field. Local recognition of an individual as a respected or influential person at the community level is not considered a "recognized expert'' for this purpose.

In presenting evidence in support of the proposed service/practice, applicants must show that the evidence presented is the best objective information available.

Justifying Selection of the Service/Practice for the Target Population

Regardless of the strength of the evidence-base for the service/practice, all applicants must show that the proposed service/practice is appropriate for the proposed target population. Ideally, this evidence will include research findings on effectiveness and acceptability specific to the proposed target population. However, if such evidence is not available, the applicant should provide a justification for using the proposed service/practice with the target population. This justification might involve, for example, a description of adaptations to the proposed service/practice based on other research involving the target population.

Justifying Adaptations/Modifications of the Proposed Service/Practice

SAMHSA/CSAP has found that a high degree of faithfulness or "fidelity'' (see Glossary) to the original model for an evidence-based service/practice increases the likelihood that positive outcomes will be achieved when the model is used by others. Therefore, SAMHSA/CSAP encourages fidelity to the original evidence-based service/practice to be implemented.

However, SAMHSA/CSAP recognizes that adaptations or modifications to the original model may be necessary for a variety of reasons:

- To allow implementers to use resources efficiently.
- To adjust for specific needs of the client population.
- To address unique characteristics of the local community where the service/practice will be implemented.

All applicants must describe and justify any adaptations or modifications to the proposed service/practice that will be made.

2.2 Services Delivery

SAMHSA/CSAP's Ecstasy and Other Club Drug Cooperative Agreement funds must be used primarily to support direct services, including the following types of activities:

■ Conducting outreach and pre-service strategies to expand access to prevention services to underserved populations. If you propose to provide only outreach and pre-service strategies, you must show that your organization is an effective and integral part of a network of service providers.
■ Purchasing or providing prevention services for populations at risk.
■ Purchasing or providing "wrap-around'' services (see Glossary) (*e.g.*, child care, transportation services) designed to improve access and retention.
■ Collecting data using specified tools to measure program effectiveness and standards to measure and monitor prevention services and costs. (No more than 20% of the total grant award may be used for data collection and evaluation.)

2.3 Infrastructure Development

Although SAMHSA/CSAP expects that its Ecstasy and Other Club Drug Cooperative Agreement funds will be used primarily for direct services, SAMHSA/CSAP recognizes that applicants may need to enhance their prevention system infrastructure in order to enhance/expand Ecstasy and Other Club Drug prevention services. Therefore, applicants may (but are not required to) propose an infrastructure development phase in year one of their projects. Infrastructure development activities may include:

■ Planning.
■ Building partnerships to ensure the success of the project and entering into service delivery and other agreements.
■ Developing or changing the infrastructure to expand prevention services.

- Training of State and local law enforcement officials, prevention and education officials, members of anti-drug coalitions, and parents.

Regardless of the infrastructure development activities proposed by the applicant, the infrastructure development phase must result in the development of a service implementation plan by the end of the first year of the project. This plan must be approved by CSAP before services may be implemented.

After the infrastructure development phase is complete, infrastructure development activities necessary to support service expansion will be limited to 15% of the total grant award.

2.4 Data and Performance Measurement

The Government Performance and Results Act of 1993 (Pub. L. 103–62, or "GPRA'') requires all Federal agencies to set program performance targets and report annually on the degree to which the previous year's targets were met. Agencies are expected to evaluate their programs regularly and to use results of these evaluations to explain their successes and failures and justify requests for funding.

To meet the GPRA requirements, SAMHSA/CSAP must collect performance data (*i.e.*, "GPRA data'') from grantees. Grantees are required to report these GPRA data to SAMHSA/CSAP on a timely basis. In your application, you must demonstrate your ability to collect and report on these measures, and you may be required to

provide some baseline data. The terms and conditions of the grant award also will specify the data to be submitted and the schedule for submission. Grantees will be required to adhere to these terms and conditions of award.

GPRA Requirements for the Infrastructure Development Phase

Grantees with an infrastructure development phase will be required to report on the following systems outcome indicators as appropriate:

—Needs assessment
—Community awareness
—Relationship building, and
—Capacity building.

CSAP is currently developing these systems outcome indicators and will seek the Office of Management and Budget approval for use of these indicators by the grantees. CSAP will then work with each grantee to determine appropriate indicators based on the activities being implemented.

GPRA Requirements for Service Delivery

For all grantees, once service delivery begins, data must be collected for those ages 12 and older using CSAP's GPRA data tool. The CSAP GPRA data tool is posted with this Request for Applications (RFA) on SAMHSA/CSAP's Web site at *http://www.samhsa.gov/grants.* A hard copy of the CSAP GPRA data tool will be included in application kits distributed by the National Clearinghouse for Alcohol and Drug Information (NCADI).

If services are being provided for individuals age 9–11, applicants must propose an approach and instrument for collecting data from these participants that is comparable to CSAP's GPRA data tool.

In addition, if grantees are targeting any of the five domains of prevention-related human behaviors and attitudes [Alcohol, Tobacco, and Other Drug Use (ATOD); Individual/Peer; Family; School; or Community], they must use additional performance measures selected from CSAP's Core Measures. All applicants must: (1) Identify which core measures the applicant proposes to collect for their program, and (2) describe their ability to collect and report data on these measures. The grantee and the CSAP project officer will jointly finalize the selection of core measures based on the nature of the program model selected and the domain within which the program will be implemented. This will be accomplished following the notice of award.

CSAP's Core Measures will be posted with this RFA on SAMHSA's Web site, *http://www.SAMHSA.gov/grants.* Applicants unable to access the document on-line should contact Beverlie Fallik at (301) 443–5827 or *bfallik@samhsa.gov;* or Sue Fialkoff at (301)443–1248 or *sfialkof@samhsa.gov.*

The following documents should be consulted when planning for data collection and reporting:

Document	Purpose	Where it can be found
CSAP GPRA Data Collection Tool.	Required data for programs providing direct services to individuals age 12 and over. Youth and adult versions in English and Spanish available.	Posted with this RFA on SAMHSA's Web site at *http://www.SAMHSA.gov/grants* and included in the application kit distributed by SAMHSA/CSAP's clearinghouse.
Core Measures Guidance	Describes how to use CSAP Core Measures	Posted with this RFA on SAMHSA's Web site at *http://www.samhsa.gov/grants* and included in the application kit distributed by SAMHSA's clearinghouse.
CSAP Core Measures Notebook.	Full description of CSAP Core Measures (200+pages)	Posted with this RFA on SAMHSA's Web site at *http://www.samhsa.gov/grants* If you are unable to access this document, contact Beverlie Fallik at (301) 443–5827 or *bfallik@samhsa.gov*; or Sue Fialkoff at (301) 443–1248 or *sfialkof@samhsa.gov*.

Applicants should be aware that SAMHSA/CSAP is working to develop a set of required core performance measures for four types of grants (*i.e.*, Services Grants, Infrastructure Grants, Best Practices Planning and Implementation Grants, and Service-to-Science Grants). As this effort proceeds, some of the data collection and reporting requirements for this program may change. All grantees will be expected to comply with any changes in data collection requirements that occur during the grantee's project period.

2.5 Grantee Meetings

You must plan to send a minimum of two people (including the Project Director) to at least one joint grantee meeting in each year of the grant, and you must include funding for this travel in your budget. At these meetings, grantees will present the results of their projects and Federal staff will provide technical assistance. Each meeting will be 3 days. These meetings will usually be held in the Washington, DC, area, and attendance is mandatory.

2.6 Evaluation

Grantees must evaluate their projects, and you are required to describe your evaluation plans in your application. The evaluation should be designed to provide regular feedback to the project to improve services. The evaluation must include both process and outcome components. Process and outcome evaluations must measure change relating to project goals and objectives over time compared to baseline information. Control or comparison groups are not required. You must consider your evaluation plan when preparing the project budget.

An ongoing goal for SAMHSA/CSAP is to assure that effective program models are developed and added to CSAP's National Registry of Effective Programs (NREP). Therefore, grantees will be strongly encouraged to adapt/replicate and evaluate their program models and submit them to NREP for review as the programs generate statistically significant findings in Years 3, 4, and 5.

Process components should address issues such as:

☐ How closely did implementation match the plan?

☐ What types of deviation from the plan occurred?

☐ What led to the deviations?

☐ What effect did the deviations have on the planned intervention and evaluation?

☐ Who provided (program, staff) what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

Outcome components should address issues such as:

☐ What was the effect of intervention on participants?

☐ What program/contextual factors were associated with outcomes?

□ What individual factors were associated with outcomes?

□ How durable were the effects?

No more than 20% of the total grant award may be used for evaluation and data collection, including GPRA.

II. Award Information

1. Award Amount

It is expected that $4.5 million will be available to fund up to 15 Ecstasy and Other Club Drug Prevention Services awards in FY 2004. The awards will be up to $300,000 in total costs (direct and indirect) per year. The actual amount available for the awards may vary, depending on unanticipated program requirements and the number and quality of the applications received.

Awards will be made for project periods of up to five years. Proposed budgets cannot exceed $300,000 in any year of the proposed project. Annual continuations will depend on the availability of funds, grantee progress in meeting program goals and objectives, and timely submission of required data and reports. Applicants proposing an infrastructure development phase in year one must have their service implementation plan approved before service delivery may begin.

2. Funding Mechanism

The Ecstasy and Other Club Drug Prevention Services awards will be made as cooperative agreements.

Role of Federal Agency: The CSAP project officer will actively participate in the program planning and program decision-making processes throughout the length of the Cooperative Agreement. In addition to the provision of program monitoring and technical assistance to the awardee, the CSAP project officer, in cooperation with the awardee, will: (1) Approve the development and selection of the service model and the services implementation plan; (2) assist with development/refinement of infrastructure development activities, if appropriate; (3) select system outcome and core measure outcomes based on the services model selected and; (4) approve the program services sustainability plan.

Role of the Awardee: Awardees will: (1) Collaborate with CSAP staff in the implementation, monitoring of all aspects of the cooperative agreement and; (2) provide CSAP (and its Program Coordinating Center) with required reporting data.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants are States, Territories, the District of Columbia, and Native American Tribal Governments. Eligibility is limited to these entities for two reasons: (1) To facilitate State and community planning and coordination, and assure that program infrastructure development and selection of ecstasy and other club drug service models are consistent with the State/Territory Strategic Prevention Framework for substance abuse prevention, and (2) to enhance program sustainability.

Although eligibility is limited to these governmental entities, these governmental entities must partner with local community organizations (public or private) in developing and implementing the grant project. Eligible applicants may submit more than one application, but only one community may be targeted in each application. States, tribes, and territories may retain up to 10% per year of the total grant award for costs associated with the administration and management of each grant submitted. At least 90% of the total grant award each year must be allocated to the community partner for implementation of services/infrastructure development at the community level.

2. Cost Sharing

Cost sharing (see Glossary) is not required in this program, and applications will not be screened out on the basis of cost sharing. However, you may include cash or in-kind contributions (see Glossary) in your proposal as evidence of commitment to the proposed project.

3. Other

3.1 Additional Eligibility Requirements

Applications must comply with the following requirements, or they will be screened out and will not be reviewed: Use of the PHS 5161–1 application; application submission requirements in Section IV–3 of this document; and formatting requirements provided in Section IV–2.3 of this document.

3.2 Evidence of Experience and Credentials

SAMHSA/CSAP believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide required services quickly and effectively. Therefore, in addition to the basic eligibility requirements specified in this announcement, applicants must meet three additional requirements related to the provision of prevention services.

The three requirements are:

- A provider organization for direct client services (e.g., substance abuse prevention services) appropriate to the grant must be involved in each application. More than one provider organization may be involved;
- Each direct service provider organization must have at least 2 years experience providing services in the geographic area(s) covered by the application, as of the due date of the application; and
- Each direct service provider organization must comply with all applicable local (city, county) and State/tribal licensing, accreditation, and certification requirements, as of the due date of the application.

Note: The above requirements apply to all service provider organizations. A license from an individual clinician will not be accepted in lieu of a provider organization's license.

In Appendix 1 of the application, you must: (1) Identify at least one experienced, licensed service provider organization; (2) include a list of all direct service provider organizations that have agreed to participate in the proposed project, including the applicant agency if the applicant is a treatment or prevention service provider organization; and (3) include the Statement of Assurance (provided in Appendix F of this announcement), signed by the authorized representative of the applicant organization identified on the face-page of the application, that all participating service provider organizations:

- Meet the 2-year experience requirement
- Meet applicable licensing, accreditation, and certification requirements, and,
- If the application is within the funding range, will provide the Government Project Officer (GPO) with the required documentation within the time specified.

If Appendix 1 of the application does not contain items (1)–(3), the application will be considered ineligible and will not be reviewed.

In addition, if, following application review, an application's score is within the fundable range for a grant award, the GPO will call the applicant and request that the following documentation be sent by overnight mail:

- A letter of commitment that specifies the nature of the participation and what service(s) will be provided from every service provider organization

that has agreed to participate in the project;

• Official documentation that all participating organizations have been providing relevant services for a minimum of 2 years before the date of the application in the area(s) in which the services are to be provided; and

• Official documentation that all participating service provider organizations comply with all applicable local (city, county) and State/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation, and certification requirements do not exist.

If the GPO does not receive this documentation within the time specified, the application will be removed from consideration for an award and the funds will be provided to another applicant meeting these requirements.

IV. Application and Submission Information

To ensure that you have met all submission requirements, a checklist is provided for your use in Appendix A of this document.

1. Address To Request Application Package

You may request a complete application kit by calling the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1–800–729–6686.

You also may download the required documents from the SAMHSA/CSAP Web site at *http://www.samhsa.gov.* Click on ''grant opportunities.''

Additional materials available on this Web site include:

• A technical assistance manual for potential applicants;

• Standard terms and conditions for SAMHSA grants;

• Guidelines and policies that relate to SAMHSA grants (*e.g.*, guidelines on cultural competence, consumer and family participation, and evaluation); and

• Enhanced instructions for completing the PHS 5161–1 application.

2. Content and Form of Application Submission

2.1 Required Documents

SAMHSA application kits include the following documents:

☐ PHS 5161–1 (revised July 2000)—Includes the face page, budget forms, assurances, certification, and checklist. Applications that are not submitted on the 5161–1 application form will be screened out and will not be reviewed.

☐ Request for Applications (RFA)—Includes instructions for the grant application. This document is the RFA.

You must use all of the above documents in completing your application.

2.2 Required Application Components

To ensure equitable treatment of all applications, applications must be complete. In order for your application to be complete, it must include the required ten application components (Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist).

☐ *Face Page*—Use Standard Form (SF) 424, which is part of the PHS 5161–1. [**Note:** Beginning October 1, 2003, applicants will need to provide a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. SAMHSA applicants will be required to provide their DUNS number on the face page of the application. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the Dun and Bradstreet Web site at *http.www.dunandbradstreet.com* or call 1–866–705–5711. To expedite the process, let Dun and Bradstreet know that you are a public/private nonprofit organization getting ready to submit a Federal grant application.]

☐ *Abstract*—Your total abstract should not be longer than 35 lines. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reporting to Congress, or press releases.

☐ *Table of Contents*—Include page numbers for each of the major sections of your application and for each appendix.

☐ *Budget Form*—Use SF 424A, which is part of the PHS 5161–1. Fill out Sections B, C, and E of the SF 424A.

☐ *Project Narrative and Supporting Documentation*—The Project Narrative describes your project. It consists of Sections A through E. Sections A-E together may not be longer than 30 pages. More detailed instructions for completing each section of the Project Narrative are provided in ''Section V—Application Review Information'' of this document.

The Supporting Documentation provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections F through I. There are no page limits for these sections, except for Section H, the Biographical Sketches/Job Descriptions.

☐ Section F—Literature Citations. This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

☐ Section G—Budget Justification, Existing Resources, Other Support. You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Be sure to show that:

○ No more than 10% of the total award is retained by the applicant to cover costs of administering the grant;

○ At least 90% of the total grant award is allocated to the community partner to implement the project;

○ No more than 15% of the total grant award will be used for infrastructure development, except during the allowable infrastructure development phase in the first year of the project; and

○ more than 20% of the total grant award will be used for data collection and evaluation (including GPRA).

The infrastructure development, data collection and evaluation costs may be shared by the State and the community partner.

■ Section H—Biographical Sketches and Job Descriptions.

○ Include a biographical sketch for the Project Director and other key positions. Each sketch should be 2 pages or less. If the person has not been hired, include a letter of commitment from the individual with a current biographical sketch.

○ Include job descriptions for key personnel. Job descriptions should be no longer than 1 page each.

○ Sample sketches and job descriptions are listed on page 22, Item 6 in the Program Narrative section of the PHS 5161–1.

■ Section I—Confidentiality and SAMHSA Participant Protection/Human Subjects. Section IV–2.4 of this document describes requirements for the protection of the confidentiality, rights and safety of participants in SAMHSA/CSAP-funded activities. This section also includes guidelines for completing this part of your application.

☐ *Appendices 1 through 3*—Use only the appendices listed below. Do not use more than 30 pages for Appendices 1 and 3. There is no page limit for Appendix 2. Do not use appendices to extend or replace any of the sections of

the Project Narrative. Reviewers will not consider them if you do.

■ Appendix 1: Letters of commitment/support. Identification of at least one experienced, licensed service provider organization. A list of all direct service provider organizations that have agreed to participate in the proposed project, including the applicant agency, if it is a treatment or prevention service provider organization. The Statement of Assurance (provided in Appendix F of this announcement) signed by the authorized representative of the applicant organization identified on the face page of the application, that assures SAMHSA that all listed providers meet the 2-year experience requirement, are appropriately licensed, accredited, and certified, and that if the application is within the funding range for an award, the applicant will send the GPO the required documentation within the specified time.

■ Appendix 2: Data Collection Instruments/Interview Protocols

■ Appendix 3: Sample Consent Forms

□ *Assurances*—Non-Construction Programs. Use Standard Form 424B found in PHS 5161–1. Applicants are required to complete the Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations, Form SMA 170. This form will be posted on SAMHSA's Web site with the RFA and provided in the application kits available at NCADI.

□ *Certifications*—Use the "Certifications'' forms found in PHS 5161–1.

□ *Disclosure of Lobbying Activities*—Use Standard Form LLL found in the PHS 5161–1. Federal law prohibits the use of appropriated funds for publicity or propaganda purposes, or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before the Congress or State legislatures. This includes "grass roots'' lobbying, which consists of appeals to members of the public suggesting that they contact their elected representatives to indicate their support for or opposition to pending legislation or to urge those representatives to vote in a particular way.

□ *Checklist*—Use the Checklist found in PHS 5161–1. The Checklist ensures that you have obtained the proper signatures, assurances and certifications and is the last page of your application.

2.3 Application Formatting Requirements

Applicants also must comply with the following basic application requirements. Applications that do not comply with these requirements will be screened out and will not be reviewed.

□ Information provided must be sufficient for review.

□ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

• Text in the Project Narrative cannot exceed 6 lines per vertical inch.

□ Paper must be white paper and 8.5 inches by 11.0 inches in size.

□ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the 30-page limit for the Project Narrative.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by 30. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

□ The 30-page limit for Appendices 1 and 3.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, following these guidelines will help reviewers to consider your application.

□ Pages should be typed single-spaced with one column per page.

□ Pages should not have printing on both sides.

□ Please use black ink and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

□ Send the original application and two copies to the mailing address in Section IV–6.1 of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

2.4 SAMHSA Confidentiality and Participant Protection Requirements and Protection of Human Subjects Regulations

Applicants must describe procedures relating to Confidentiality, Participant Protection and the Protection of Human Subjects Regulations in Section I of the application, using the guidelines provided below. Problems with confidentiality, participant protection, and protection of human subjects identified during peer review of the application may result in the delay of funding.

Confidentiality and Participant Protection: All applicants *must* describe how they will address requirements for each of the following elements relating to confidentiality and participant protection.

1. Protect Clients and Staff from Potential Risks

■ Identify and describe any foreseeable physical, medical, psychological, social and legal risks or potential adverse effects as a result of the project itself or any data collection activity.

■ Describe the procedures you will follow to minimize or protect participants against potential risks, including risks to confidentiality.

■ Identify plans to provide guidance and assistance in the event there are adverse effects to participants.

■ Where appropriate, describe alternative treatments and procedures that may be beneficial to the participants. If you choose not to use these other beneficial treatments, provide the reasons for not using them.

2. Fair Selection of Participants

■ Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes homeless youth, foster children, children of substance abusers, pregnant women, or other targeted groups.

■ Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people

in institutions, prisoners, and individuals who are likely to be particularly vulnerable to HIV/AIDS.

■ Explain the reasons for including or excluding participants.

■ Explain how you will recruit and select participants. Identify who will select participants.

3. Absence of Coercion

■ Explain if participation in the project is voluntary or required. Identify possible reasons why participation is required, for example, court orders requiring people to participate in a program.

■ If you plan to compensate participants, state how participants will be awarded incentives (*e.g.*, money, gifts, *etc.*).

■ State how volunteer participants will be told that they may receive services intervention even if they do not participate in or complete the data collection component of the project.

4. Data Collection

■ Identify from whom you will collect data (*e.g.*, from participants themselves, family members, teachers, others). Describe the data collection procedures and specify the sources for obtaining data (*e.g.*, school records, interviews, psychological assessments, questionnaires, observation, or other sources). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.

■ Identify what type of specimens (*e.g.*, urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

■ Provide in Appendix 2, ''Data Collection Instruments/Interview Protocols,'' copies of all available data collection instruments and interview protocols that you plan to use.

5. Privacy and Confidentiality

■ Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.

■ Describe:

○ How you will use data collection instruments.

○ Where data will be stored.

○ Who will or will not have access to information.

○ How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

Note: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

6. Adequate Consent Procedures

■ List what information will be given to people who participate in the project. Include the type and purpose of their participation. Identify the data that will be collected, how the data will be used and how you will keep the data private.

■ State:

○ Whether or not their participation is voluntary.

○ Their right to leave the project at any time without problems.

○ Possible risks from participation in the project.

○ Plans to protect clients from these risks.

■ Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

Note: If the project poses potential physical, medical, psychological, legal, social or other risks, you must obtain written informed consent.

■ Indicate if you will obtain informed consent from participants or assent from minors along with consent from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

■ Include, as appropriate, sample consent forms that provide for: (1) Informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information. The sample forms must be included in Appendix 3, ''Sample Consent Forms'', of your application. If needed, give English translations.

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

■ Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?

■ Additionally, if other consents (*e.g.*, consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7. Risk/Benefit Discussion

Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

Protection of Human Subjects Regulations: Depending on the evaluation design you propose in your application, you may have to comply with the Protection of Human Subjects Regulations (45 CFR part 46).

Applicants whose projects must comply with the Protection of Human Subjects Regulations must describe the process for obtaining Institutional Review Board (IRB) approval fully in their applications. While IRB approval is not required at the time of grant award, these applicants will be required, as a condition of award, to provide the documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP) and the IRB approval has been received prior to enrolling any clients in the proposed project.

Additional information about Protection of Human Subjects Regulations can be obtained on the web at *http://ohrp.osophs.dhhs.gov.* You may also contact OHRP by e-mail (*ohrp@osophs.dhhs.gov*) or by phone (301/496–7005).

3. Submission Dates and Times

Applications are due by June 18, 2004.

Your application must be received by the application deadline. Applications received after this date must have a proof-of-mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing.

You will be notified by postal mail that your application has been received.

Applications not received by the application deadline or not postmarked by a week prior to the application deadline will be screened out and will not be reviewed.

4. Intergovernmental Review (E.O. 12372) Requirements

Executive Order 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100, sets up a system for State and local review of applications for Federal financial assistance. A current listing of State Single Points of Contact (SPOCs) is

included in the application kit and can be downloaded from the Office of Management and Budget (OMB) Web site at *http://www.whitehouse.gov/omb/grants/spoc.html.*

■ Check the list to determine whether your State participates in this program. You do not need to do this if you are a federally recognized Indian tribal government.

■ If your State participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the State's review process.

■ For proposed projects serving more than one State, you are advised to contact the SPOC of each affiliated State.

■ The SPOC should send any State review process recommendations to the following address within 60 days of the application deadline: Substance Abuse and Mental Health Services Administration, Office of Program Services, Review Branch, 5600 Fishers Lane, Room 17–89, Rockville, Maryland, 20857, ATTN: SPOC—Funding Announcement No. SP–04–004.

5. Funding Limitations/Restrictions

Cost principles describing allowable and unallowable expenditures for Federal grantees, including SAMHSA grantees, are provided in the following documents:

■ Institutions of Higher Education: OMB Circular A–21

■ State and Local Governments: OMB Circular A–87

■ Nonprofit Organizations: OMB Circular A–122

■ Appendix E Hospitals: 45 CFR Part 74

In addition, SAMHSA Services Grant recipients must comply with the following funding restrictions:

■ No more than 15% of the total grant award may be used for developing the infrastructure necessary for expansion of services, except during the allowable infrastructure development phase in year one of the project. (There is no limit on expenditure for infrastructure development during this phase of the project.)

■ No more than 20% of the total grant award may be used for evaluation and data collection (including GPRA). These costs may be shared by the applicant and the community partner.

■ No more than 10% of the total grant award may be retained by the applicant for costs associated with the administration and management of the grant.

■ At least 90% of the total grant award must be allocated to the community partner for implementation of services/infrastructure development at the community level.

Grant funds must be used for purposes supported by the program and may not be used to:

■ Pay for any lease beyond the project period.

■ Provide services to incarcerated populations (defined as those persons in jail, prison, detention facilities, or in custody where they are not free to move about in the community).

■ Pay for the purchase or construction of any building or structure to house any part of the program. (Applicants may request up to $75,000 for renovations and alterations of existing facilities, if necessary and appropriate to the project.)

■ Pay for incentives to induce individuals to enter services. However, a grantee or service provider may provide up to $20 or equivalent (coupons, bus tokens, gifts, child care, and vouchers) to individuals as incentives to participate in required data collection follow-up. This amount may be paid for participation in each required interview.

■ Implement syringe exchange programs, such as the purchase and distribution of syringes and/or needles.

■ Pay for pharmacologies for HIV antiretroviral therapy, sexually transmitted diseases (STD)/sexually transmitted illnesses (STI), TB, and hepatitis B and C, or for psychotropic drugs.

6. Other Submission Requirements

6.1 Where To Send Applications

Send applications to the following address: Substance Abuse and Mental Health Services Administration, Office of Program Services, Review Branch, 5600 Fishers Lane, Room 17–89, Rockville, Maryland, 20857.

Be sure to include the funding announcement number (SP 04–004) in item number 10 on the face page of the application. If you require a phone number for delivery, you may use (301) 443–4266.

6.2 How To Send Applications

Mail an original application and 2 copies (including appendices) to the mailing address provided above. The original and copies must not be bound. Do not use staples, paper clips, or fasteners. Nothing should be attached, stapled, folded, or pasted.

You must use a recognized commercial or governmental carrier. Hand carried applications will not be accepted. Faxed or e-mailed applications will not be accepted.

V. Application Review Information

1. Evaluation Criteria

Your application will be reviewed and scored according to the quality of your response to the requirements listed below for developing the Project Narrative (Sections A–E). These sections describe what you intend to do with your project.

■ In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program. These are to be used instead of the "Program Narrative'' instructions found in the PHS 5161–1.

■ The Project Narrative (Sections A–E) together may be no longer than 30 pages.

■ You must use the five sections/headings listed below in developing your Project Narrative. Be sure to place the required information in the correct section, or it will not be considered. Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

■ Reviewers will be looking for evidence of cultural competence in each section of the Project Narrative. Points will be assigned based on how well you address the cultural competence aspects of the evaluation criteria. SAMHSA guidelines for cultural competence can be found on the SAMHSA Web site at *http://www.samhsa.gov/grants.*

■ The Supporting Documentation you provide in Sections F–I and Appendices 1–5 will be considered by reviewers in assessing your response, along with the material in the Project Narrative.

■ The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Bullet statements in each section do not have points assigned to them. They are provided to invite the attention of applicants and reviewers to important areas within the criterion.

Section A: Statement of Need (10 Points)

■ Describe the target population (see Glossary) as well as the geographic area to be served, and justify the selection of both. Include the numbers to be served and demographic information. Clearly identify the target community that is partnering with the applicant organization in developing and implement the proposed project. Discuss the target population's language, beliefs, norms and values, as well as socioeconomic factors that must be considered in delivering programs to this population.

■ Describe the nature of the problem and extent of the need for the target population based on data. The statement of need should include a clearly established baseline for the project. Documentation of need may come from a variety of qualitative and quantitative sources. The quantitative data could come from local data or trend analyses, State data (*e.g.*, from State Needs Assessments), and/or national data (*e.g.*, from SAMHSA's National Household Survey on Drug Abuse and Health or from National Center for Health Statistics/Centers for Disease Control reports). For data sources that are not well known, provide sufficient information on how the data were collected so reviewers can assess the reliability and validity of the data.

■ Describe how the proposed project is guided by the Drug Enforcement Agency's (DEA) assessment of the incidence, disposition, and prevalence of ecstasy and other club drug use within the State, Tribal area, or Territory. (Information in the DEA assessments is available on the DEA Web site at *www.dea.gov/pubs/state_factsheets.html.)*

■ Applicants proposing an infrastructure development phase must document the need for infrastructure development to improve effective Ecstasy and Other Club Drug Use prevention services implementation in the target community. This documentation should include a description of the service gaps, barriers and other problems related to need for infrastructure development and how they will be overcome.

Section B: Proposed Evidence-Based Service/Practice (30 Points)

■ Clearly state the purpose, goals and objectives of your proposed project. Describe how achievement of goals will produce meaningful and relevant results (*e.g.*, increase access, availability, prevention, outreach, pre-services, and/or intervention).

■ Identify the evidenced based service/practice that you propose to implement. Describe the evidence-base for the proposed service/practice and show that it incorporates the best objective information available regarding effectiveness and acceptability. Follow the instructions provided in #1, #2 or #3 below, as appropriate:

1. *If you are proposing to implement a service/practice included in NREP (see Appendix C)*, simply identify the practice and state the source from which it was selected. You do not need to provide further evidence of effectiveness.

2. *If you are providing evidence that includes scientific studies published in the peer-reviewed literature or other studies that have not been published, describe the extent to which:*

—The service/practice has been evaluated and the quality of the evaluation studies (*e.g.*, whether they are descriptive, quasi-experimental studies, or experimental studies)
—The services/practice has demonstrated positive outcomes and for what populations the positive outcomes have been demonstrated
—The service/practice has been documented (*e.g.*, through development of guidelines, tool kits, treatment protocols, and/or manuals) and replicated
—Fidelity measures have been developed (*e.g.*, no measures developed, key components identified, or fidelity measures developed)

3. *If you are providing evidence based on a formal consensus process involving recognized experts in the field, describe:*

—The experts involved in developing consensus on the proposed service/practice (*e.g.*, members of an expert panel formally convened by SAMHSA, NIH, the Institute of Medicine or other nationally recognized organization). The consensus must have been developed by a group of experts whose work is recognized and respected by others in the field. Local recognition of an individual as a respected or influential person at the community level is not considered a "recognized expert'' for this purpose.
—The nature of the consensus that has been reached and the process used to reach consensus
—The extent to which the consensus has been documented (*e.g.*, in a consensus panel report, meeting minutes, or an accepted standard practice in the field)
—Any empirical evidence (whether formally published or not) supporting the effectiveness of the proposed service/practice
—The rationale for concluding that further empirical evidence does not exist to support the effectiveness of the proposed service/practice

■ Justify the use of the proposed service/practice for the target population. Describe and justify any adaptations necessary to meet the needs of the target population as well as evidence that such adaptations will be effective for the target population.

■ Identify and justify any additional adaptations or modifications to the proposed service/practice.

■ Describe how the proposed project will address issues of age, race, ethnicity, culture, language, sexual orientation, disability, literacy, and gender in the target population, while retaining fidelity to the chosen practice.

■ Demonstrate how the proposed service/practice will meet your goals and objectives. Provide a logic model (see Glossary) that links need, the services or practice to be implemented, and outcomes.

Section C: Proposed Implementation Approach (25 Points)

■ Describe how the proposed service or practice will be implemented. Provide a realistic time line for the project (chart or graph) showing key activities, milestones, and responsible staff. [**Note:** The time line should be part of the Project Narrative. It should not be placed in an appendix.]

■ If applicable, describe the infrastructure development phase and how it will be implemented. Discuss how the infrastructure development phase will lay the groundwork for implementation of the proposed service or practice. Show that the infrastructure development phase will be completed by the end of the first year of the project.

■ Describe how the community partner has been involved in developing the grant project and how it will be involved in implementing the evidence-based practice and infrastructure development activity(ies), if appropriate.

■ Clearly state the unduplicated number of individuals you propose to serve (annually and over the entire project period) with grant funds, including the types and numbers of services to be provided and anticipated outcomes. Describe how the target population will be identified, recruited, and retained.

■ Describe how members of the target population helped prepare the application, and how they will help plan, implement, and evaluate the project.

■ Describe how the project components will be embedded within the existing service delivery system, including other SAMHSA-funded projects, if applicable. Identify any other organizations that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include letters of commitment from community organizations supporting the project in Appendix 1. Identify any cash or in-kind contributions that will be made to the project by the applicant or other partnering organizations.

■ For applicants that are not proposing an infrastructure development phase, show that the necessary groundwork (*e.g.*, planning, consensus development, development of memoranda of agreement, identification of potential facilities) has been completed or is near completion so that the project can be implemented and service delivery can begin as soon as possible and no later than 4 months after grant award.

■ Describe the potential barriers to successful conduct of the proposed project and how you will overcome them.

■ Provide a plan to secure resources to sustain the proposed project when Federal funding ends.

Section D: Staff and Organizational Experience (20 Points)

■ Discuss the capability and experience of the applicant organization and other participating organizations with similar projects and populations, including experience in providing culturally appropriate/competent services and implementing effective prevention interventions.

■ Provide a list of staff who will participate in the project, showing the role of each and their level of effort and qualifications. Include the Project Director and other key personnel, such as the evaluator and treatment/prevention personnel.

■ Describe the racial/ethnic characteristics of key staff and indicate if any are members of the target population/community. If the target population is multi-linguistic, indicate if the staffing pattern includes bilingual and bicultural individuals.

■ Describe the resources available for the proposed project (*e.g.*, facilities, equipment), and provide evidence that services will be provided in a location that is adequate, accessible, compliant with the Americans with Disabilities Act (ADA), and amenable to the target population.

■ Describe how the applicant has worked with local communities to plan, coordinate and implement effective prevention activities.

■ Describe the applicant's ability to utilize data to monitor services and costs.

Section E: Evaluation and Data (15 Points)

■ Document your ability to collect and report on the required performance measures.

■ Identify and justify the Core Measures appropriate to your project and document your ability to collect and report those measures.

■ Describe plans for data collection, management, analysis, interpretation and reporting. Describe the existing approach to the collection of data, along with any necessary modifications. Be sure to include data collection instruments/interview protocols in Appendix 2.

■ Discuss the reliability and validity of evaluation methods and instrument(s) in terms of the gender/age/culture of the target population.

■ Describe the process and outcome evaluation, including assessments of implementation and individual outcomes. Show how the evaluation will be integrated with requirements for collection and reporting of performance data, including data required by SAMHSA to meet GPRA requirements.

■ Describe how the evaluation will be used to ensure the fidelity to the practice.

■ Provide a per-person or unit cost of the project to be implemented, based on the applicant's actual costs and projected costs over the life of the project.

Note: Although the budget for the proposed project is not a review criterion, the Review Group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered.

2. Review and Selection Process

SAMHSA applications are peer-reviewed according to the review criteria listed above. For those programs where the individual award is over $100,000, applications must also be reviewed by the appropriate National Advisory Council.

Decisions to fund a grant are based on:

■ The strengths and weaknesses of the application as identified by peer reviewers and, when applicable, approved by the appropriate National Advisory Council;

■ Availability of funds;

■ Equitable distribution of awards in terms of geography (including urban, rural and remote settings) and balance among target populations and program size; and

■ After applying the aforementioned criteria, the following method for breaking ties: When funds are not available to fund all applications with identical scores, SAMHSA will make award decisions based on the application(s) that received the greatest number of points by peer reviewers on the evaluation criterion in Section V–1 with the highest number of possible points (Proposed Evidence-Based Service/Practice—30 points). Should a tie still exist, the evaluation criterion with the next highest possible point value will be used, continuing sequentially to the evaluation criterion with the lowest possible point value, should that be necessary to break all ties. If an evaluation criterion to be used for this purpose has the same number of possible points as another evaluation criterion, the criterion listed first in Section V–1 will be used first.

VI. Award Administration Information

1. Award Notices

After your application has been reviewed, you will receive a letter from SAMHSA through postal mail that describes the general results of the review, including the score that your application received.

If you are approved for funding, you will receive an additional notice, the Notice of Grant Award, signed by SAMHSA's Grants Management Officer. The Notice of Grant Award is the sole obligating document that allows the grantee to receive Federal funding for work on the grant project. It is sent by postal mail and is addressed to the contact person listed on the face page of the application.

If you are not funded, you can re-apply if there is another receipt date for the program.

2. Administrative and National Policy Requirements

■ You must comply with all terms and conditions of the grant award. SAMHSA's standard terms and conditions are available on the SAMHSA Web site at *www.samhsa.gov/grants/2004/useful_info.asp.*

■ Depending on the nature of the specific funding opportunity and/or the proposed project as identified during review, additional terms and conditions may be identified negotiated with the grantee prior to grant award. These may include, for example:

○ Actions required to be in compliance with human subjects requirements;

○ Requirements relating to additional data collection and reporting;

○ Requirements relating to participation in a cross-site evaluation; or

○ Requirements to address problems identified in review of the application.

■ You will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the grant

and the amount of any continuation award. Failure to meet stated goals and objectives may result in suspension or termination of the grant award, or in reduction or withholding of continuation awards.

■ In an effort to improve access to funding opportunities for applicants, SAMHSA is participating in the U.S. Department of Health and Human Services "Survey on Ensuring Equal Opportunity for Applicants.'' This survey is included in the application kit for SAMHSA grants. Applicants are encouraged to complete the survey and return it, using the instructions provided on the survey form.

3. Reporting Requirements

3.1 Progress and Financial Reports

■ Grantees must provide annual and final progress reports. The final report must summarize information from the annual reports, describe the accomplishments of the project, and describe next steps for implementing plans developed during the grant period.

■ Grantees must provide annual and final financial status reports. These reports may be included as separate sections of annual and final progress reports or can be separate documents. Because SAMHSA is extremely interested in ensuring that treatment or prevention services can be sustained, your financial reports should explain plans to ensure the sustainability (see Glossary) of efforts initiated under this grant. Initial plans for sustainability should be described in year 01. In each subsequent year, you should describe the status of your project, as well as the successes achieved and obstacles encountered in that year.

■ SAMHSA will provide guidelines and requirements for these reports to grantees at the time of award and at the initial grantee orientation meeting after award. SAMHSA staff will use the information contained in the reports to determine the grantee's progress toward meeting its goals.

3.2 Government Performance and Results Act (GPRA)

The Government Performance and Results Act (GPRA) mandates accountability and performance-based management by Federal agencies. To meet the GPRA requirements, SAMHSA must collect performance data (*i.e.*, "GPRA data'') from grantees. These requirements are specified in Section I–2.4 (Data and Performance Measurement) of this document.

3.3 Publications

If you are funded under this grant program, you are required to notify the Government Project Officer (GPO) and SAMHSA's Publications Clearance Officer (301–443–8596) of any materials based on the SAMHSA-funded grant project that are accepted for publication.

In addition, SAMHSA requests that grantees:

■ Provide the GPO and SAMHSA Publications Clearance Officer with advance copies of publications.

■ Include acknowledgment of the SAMHSA grant program as the source of funding for the project.

■ Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services, and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance abuse treatment/substance abuse prevention/mental health services community.

VII. Agency Contacts

For questions about program issues, contact: Tom DeLoe, Ph.D., SAMHSA/CSAP, 5600 Fishers Lane, Rockwall II, Suite 1075, Rockville, MD 20857, 301–443–9110, E-mail: *tdeloe@samhsa.gov.*

For questions on grants management issues, contact: Edna Frazier, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857, (301) 443–6816, *efrazier@samhsa.gov.*

Appendix A—Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review. In addition to these formatting requirements, programmatic requirements (*e.g.*, relating to eligibility) may be stated in the specific funding announcement. Please check the entire funding announcement before preparing your application.

☐ Use the PHS 5161–1 application.

☐ Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.

☐ Information provided must be sufficient for review.

☐ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

• Text in the Project Narrative cannot exceed 6 lines per vertical inch.

☐ Paper must be white paper and 8.5 inches by 11.0 inches in size.

☐ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the specific funding announcement.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

☐ The page limit for Appendices stated in the specific funding announcement cannot be exceeded.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

☐ The 10 application components required for SAMHSA applications should be included. These are:

• Face Page (Standard Form 424, which is in PHS 5161–1).

• Abstract.

• Table of Contents.

• Budget Form (Standard Form 424A, which is in PHS 5161–1).

• Project Narrative and Supporting Documentation.

• Appendices.

• Assurances (Standard Form 424B, which is in PHS 5161–1).

• Certifications (a form within PHS 5161–1).

• Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161–1).

• Checklist (a form in PHS 5161–1).

☐ Applications should comply with the following requirements:

• Provisions relating to confidentiality, participant protection and the protection of human subjects specified in Section IV–2.4 of the FY 2004 standard funding announcements.

• Budgetary limitations as specified in Section I, II, and IV–5 of the FY 2004 standard funding announcements.

• Documentation of nonprofit status as required in the PHS 5161–1.

☐ Pages should be typed single-spaced with one column per page.

☐ Pages should not have printing on both sides.

☐ Please use black ink and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

☐ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD–ROMs.

Appendix B—Glossary

Best Practice: Best practices are practices that incorporate the best objective information currently available regarding effectiveness and acceptability.

Catchment Area: A catchment area is the geographic area from which the target population to be served by a program will be drawn.

Cooperative Agreement: A cooperative agreement is a form of Federal grant. Cooperative agreements are distinguished from other grants in that, under a cooperative agreement, substantial involvement is anticipated between the awarding office and the recipient during performance of the funded activity. This involvement may include collaboration, participation, or intervention in the activity. HHS awarding offices use grants or cooperative agreements (rather than contracts) when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant or cooperative agreement is the public, as opposed to the Federal Government.

Cost Sharing or Matching: Cost sharing refers to the value of allowable non-Federal contributions toward the allowable costs of a Federal grant project or program. Such contributions may be cash or in-kind contributions. For SAMHSA grants, cost sharing or matching is not required, and applications will not be screened out on the basis of cost sharing. However, applicants often include cash or in-kind contributions in their proposals as evidence of commitment to the proposed project. This is allowed, and this information may be considered by reviewers in evaluating the quality of the application.

Fidelity: Fidelity is the degree to which a specific implementation of a program or practice resembles, adheres to, or is faithful to the evidence-based model on which it is based. Fidelity is formally assessed using rating scales of the major elements of the evidence-based model. A toolkit on how to develop and use fidelity instruments is available from the SAMHSA-funded Evaluation Technical Assistance Center at http://tecathsri.org or by calling (617) 876–0426.

Grant: A grant is the funding mechanism used by the Federal Government when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant or cooperative agreement is the public, as opposed to the Federal Government.

In-Kind Contribution: In-kind contributions toward a grant project are non-cash contributions (*e.g.*, facilities, space, services) that are derived from non-Federal sources, such as State or sub-State non-Federal revenues, foundation grants, or contributions from other non-Federal public or private entities.

Logic Model: A logic model is a diagrammatic representation of a theoretical framework. A logic model describes the logical linkages among program resources, conditions, strategies, short-term outcomes, and long-term impact. More information on how to develop logics models and examples can be found through the resources listed in Appendix G.

Practice: A practice is any activity, or collective set of activities, intended to improve outcomes for people with or at risk for substance abuse and/or mental illness. Such activities may include direct service provision, or they may be supportive activities, such as efforts to improve access to and retention in services, organizational efficiency or effectiveness, community readiness, collaboration among stakeholder groups, education, awareness, training, or any other activity that is designed to improve outcomes for people with or at risk for substance abuse or mental illness.

Practice Support System: This term refers to contextual factors that affect practice delivery and effectiveness in the pre-adoption phase, delivery phase, and post-delivery phase, such as (a) community collaboration and consensus building, (b) training and overall readiness of those implementing the practice, and (c) sufficient ongoing supervision for those implementing the practice.

Stakeholder: A stakeholder is an individual, organization, constituent group, or other entity that has an interest in and will be affected by a proposed grant project.

Strategic Prevention Framework: This term refers to a SAMHSA/CSAP initiative to encourage States to develop strategic plans to prevent/reduce the use of alcohol, tobacco and other drugs. This process will include needs assessment, capacity building, planning, implementation, and evaluation.

Sustainability: Sustainability is the ability to continue a program or practice after SAMHSA grant funding has ended.

Target Population: The target population is the specific population of people whom a particular program or practice is designed to serve or reach.

Wraparound Service: Wraparound services are non-clinical supportive services—such as child care, vocational, educational, and transportation services—that are designed to improve the individual's access to and retention in the proposed project.

Appendix C—National Registry of Effective Programs

To help SAMHSA's constituents learn more about science-based programs, SAMHSA's Center for Substance Abuse Prevention (CSAP) created a National Registry of Effective Programs (NREP) to review and identify effective programs. NREP seeks candidates from the practice community and the scientific literature. While the initial focus of NREP was substance abuse prevention programming, NREP has expanded its scope and now includes prevention and treatment of substance abuse and of co-occurring substance abuse and mental disorders, and psychopharmacological programs and workplace programs.

NREP includes three categories of programs: Effective Programs, Promising Programs, and Model Programs. Programs defined as Effective have the option of becoming Model Programs if their developers choose to take part in SAMHSA dissemination efforts. The conditions for making that choice, together with definitions of the three major criteria, are as follows.

Promising Programs have been implemented and evaluated sufficiently and are scientifically defensible. They have positive outcomes in preventing substance abuse and related behaviors. However, they have not yet been shown to have sufficient rigor and/or consistently positive outcomes required for Effective Program status. Nonetheless, Promising Programs are eligible to be elevated to Effective/Model status after review of additional documentation regarding program effectiveness. Originated from a range of settings and spanning target populations, Promising Programs can guide prevention, treatment, and rehabilitation.

Effective Programs are well-implemented, well-evaluated programs that produce consistently positive pattern of results (across domains and/or replications). Developers of Effective Programs have yet to help SAMHSA/CSAP disseminate their programs, but may do so themselves.

Model Programs are also well-implemented, well-evaluated programs, meaning they have been reviewed by NREP according to rigorous standards of research. Their developers have agreed with SAMHSA/CSAP to provide materials, training, and technical assistance for nationwide implementation. That helps ensure the program is carefully implemented and likely to succeed.

Programs that have met the NREP standards for each category can be identified by accessing the NREP Model Programs Web site at *www.modelprograms.samhsa.gov.*

Appendix F—Statement Of Assurance

As the authorized representative of the applicant organization, I assure SAMHSA that if {insert name of organization} application is within the funding range for a grant award, the organization will provide the SAMHSA Government Project Officer (GPO) with the following documents. I understand that if this documentation is not received by the GPO within the specified timeframe, the application will be removed from consideration for an award and the funds will be provided to another applicant meeting these requirements.

- A letter of commitment that specifies the nature of the participation and what service(s) will be provided from every service provider organization, listed in Appendix 1 of the application, that has agreed to participate in the project;
- Official documentation that all service provider organizations participating in the project have been providing relevant services for a minimum of 2 years prior to the date of the application in the area(s) in which services are to be provided. Official documents must definitively establish that the organization has provided relevant services for the last 2 years; and
- Official documentation that all participating service provider organizations are in compliance with all local (city, county) and State/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation, and certification requirements do not exist. (Official documentation is a copy of each service provider organization's license, accreditation, and certification. Documentation of accreditation will not be accepted in lieu of an organization's license. A statement by, or letter from, the applicant organization or from a provider organization attesting to compliance with licensing, accreditation and certification or that no licensing, accreditation, certification requirements exist *does not* constitute adequate documentation.)

Appendix G—Logic Model Resources

Chen, W.W., Cato, B.M., & Rainford, N. (1998–9). Using a logic model to plan and evaluate a community intervention program: A case study. International Quarterly of Community Health Education, 18(4), 449–458.

Edwards, E.D., Seaman, J.R., Drews, J., & Edwards, M.E. (1995). A community approach for Native American drug and alcohol prevention programs: A logic model framework. Alcoholism Treatment Quarterly, 13(2), 43–62.

Hernandez, M. & Hodges, S. (2003). Crafting Logic Models for Systems of Care: Ideas into Action. [Making children's mental health services successful series, volume 1]. Tampa, FL: University of South Florida, The Louis de la Parte Florida Mental Health Institute, Department of Child & Family Studies. *http://cfs.fmhi.usf.edu* or phone (813) 974–4651.

Hernandez, M. & Hodges, S. (2001). Theory-based accountability. In M. Hernandez & S. Hodges (Eds.), Developing Outcome Strategies in Children's Mental Health, pp. 21–40. Baltimore: Brookes.

Julian, D.A. (1997). Utilization of the logic model as a system level planning and evaluation device. Evaluation and Planning, 20(3), 251–257.

Julian, D.A., Jones, A., & Deyo, D. (1995). Open systems evaluation and the logic model: Program planning and evaluation tools. Evaluation and Program Planning, 18(4), 333–341.

Patton, M.Q. (1997). Utilization-Focused Evaluation (3rd Ed.), pp. 19, 22, 241. Thousand Oaks, CA: Sage.

Wholey, J.S., Hatry, H.P., Newcome, K.E. (Eds.) (1994). Handbook of Practical Program Evaluation. San Francisco, CA: Jossey-Bass Inc.

Dated: April 2, 2004.

Daryl Kade,

Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Funding Opportunity Title: Notice of Funding Availability (NOFA) for the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative (Short Title: NCTSI—National Center)

Announcement Type: Initial.

Funding Opportunity Number: SM 04–008.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Due Date for Application: June 10, 2004.

Note: Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 9, 2004.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2004 funds for the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, are also available at the Internet site: *http://www.grants.gov.*

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grant Program Announcement (INF–04 PA [MOD]), and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The INF–04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the National Center for Child Traumatic Stress of the National Child Traumatic Stress Initiative. Additional instructions and specific requirements for this funding opportunity are described below.

I. Funding Opportunity Description

Authority: Section 582 of the Public Health Service Act, as amended and subject to the availability of funds.

The National Center for Child Traumatic Stress of National Child Traumatic Stress Initiative (NCTSI—National Center) is one of SAMHSA's Infrastructure Grants. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse services systems to support effective programs and services. The purpose of the NCTSI—National Center grant is to support funding of a national coordinating center for the NCTSI network that will provide leadership, coordination, and support for collaboration of the NCTSI centers. The national coordinating center will develop and implement a framework and organizational procedures for communication and collaboration among Network centers to promote and sustain a comprehensive approach to identifying, improving, developing, and/or evaluating child trauma treatment interventions and services approaches. The national coordinating center will further develop the national capacity for training in implementing effective treatment and service delivery and develop and disseminate informational resources and other products on child and adolescent traumatic stress to professionals, policy makers, and the public.

In providing leadership for the national Network, the national coordinating center will implement the framework and organizational procedures for communication and collaboration among Network centers. This program will also enable the national coordinating center to coordinate and integrate centers funded subsequent to the original cohort into the Network. The functions of the national coordinating center are to:

- Provide leadership to the Network and strengthen the Network's ability to support high-priority, results-oriented collaborative projects that are essential for the success of the Initiative;