SUMMARY: The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to reduce the impact of substance abuse and mental illness on America’s communities. Established in 1992, the Agency was directed by Congress to target effective substance abuse and mental health services to the people most in need, and to translate research in these areas more effectively and more rapidly into the general health care system. The National Registry of Evidence-based Programs and Practices (NREPP) is a key public resource. SAMHSA has developed to help meet this directive. This notice announces NREPP’s open submission period for Fiscal Year 2012, during which developers of interventions may submit an application for a potential review. The notice explains how submissions will be screened and selected, and provides guidance on the submission process. Potential applicants should be aware that this notice includes updated information relating to the eligibility of interventions and the review process that supersedes guidance provided in earlier Federal Register notices.

FOR FURTHER INFORMATION CONTACT: Kevin D. Hennessy, Ph.D., Science to Service Coordinator, Center for Behavioral Health Statistics and Quality, SAMHSA, 1 Choke Cherry Road, Room 2–1017, Rockville, MD 20857, telephone 240–276–2234.

Rose Shannon, Director, Division of Executive Correspondence.

Substance Abuse and Mental Health Services Administration’s National Registry of Evidence-Based Programs and Practices (NREPP): Open Submission Period for Fiscal Year 2012

Background

The Substance Abuse and Mental Health Services Administration’s (SAMHSA) National Registry of Evidence-based Programs and Practices (NREPP) is a voluntary rating system designed to provide the public with reliable information about interventions that promote mental health or prevent or treat mental disorders, substance abuse, substance use disorders, and/or co-occurring disorders. Programs and practices that are accepted for inclusion in the registry undergo two independent review processes in which their (1) Quality of research and (2) readiness for dissemination are evaluated and rated. The results of these reviews are published on the NREPP Web site (http://nrepp.samhsa.gov).

It should be noted that inclusion in NREPP does not constitute endorsement of an intervention by SAMHSA. Moreover, since NREPP has not reviewed all interventions, the use of NREPP as an exclusive or exhaustive list of interventions is not appropriate. Policymakers and funders in particular are discouraged from limiting contracted providers and/or potential grantees to selecting only among NREPP interventions.

This notice announces the next open submission period during which SAMHSA will consider and accept new applications for review, describes the minimum requirements and other considerations that will be used in screening and selecting interventions, and provides guidance on the submission process.

Dates of Open Submission Period

SAMHSA has established a 3-month period for receipt of NREPP submissions for Fiscal Year 2012 that will begin November 1, 2011, and end February 1, 2012. Interventions submitted after February 1, 2012, will not be considered during this submission cycle. Program developers, researchers, and others interested in submitting an intervention should read this notice for information about current minimum requirements, and examine the information provided on the NREPP Web site about the review process and criteria (http://nrepp.samhsa.gov/Reviews.aspx) and guidance for preparing an intervention for submission (http://nrepp.samhsa.gov/SubmissionCourse.aspx). The selection of interventions will take place after the closing of the open submission period, and applicants will be informed of their acceptance status at that time. The number of reviews conducted will depend on the availability of funds, with the final selection of interventions and the timing of reviews to be determined at the discretion of SAMHSA.

In submitting an intervention, applicants understand that the results of NREPP reviews are considered public information and will be posted on the NREPP Web site. Once a review is completed, the applicant will be provided with a summary document (“intervention summary”) that presents ratings and descriptive information about the intervention. Anyone that consents to a review is expected to authorize publication of the intervention summary on the NREPP Web site. If a summary is completed and consent is not given to publish the summary, a statement to that effect will be posted on the NREPP Web site.

Applicants are encouraged to view examples of NREPP intervention summaries on the NREPP Web site to become familiar with the end product of the review process.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Registry of Evidence-Based Programs and Practices

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


SUMMARY: The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to reduce...
Minimum Requirements
To be considered for review, interventions must meet four minimum requirements:
1. The intervention has produced one or more positive behavioral outcomes (p \leq .05) in mental health, mental disorders, substance abuse, or substance use disorders among individuals, communities, or populations.
2. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. Experimental designs require random assignment, a control or comparison group, and pre- and postintervention assessments. Quasi-experimental designs do not require random assignment, but do require a comparison or control group and pre- and postintervention assessments; this category includes longitudinal/multiple time series designs with at least three preintervention or baseline measurements and at least three postintervention or follow-up measurements. Studies that are based on single group, pre-/posttest designs do not meet this requirement.
3. The results of these studies have been published in a peer-reviewed journal or other professional publication, or documented in a comprehensive evaluation report. Comprehensive evaluation reports must include a review of the literature, theoretical framework, purpose, methodology, findings/results with statistical analysis and p values for significant outcomes, discussion, and conclusions. Submissions must include information that can be rated according to the six Quality of Research criteria identified on the NREPP Web site.
4. Implementation materials, training and support resources, and quality assurance procedures have been developed and are ready for use by the public.

Applicants are required to provide documentation at the time of submission that demonstrates the intervention meets these minimum requirements. Table 1 lists examples of appropriate supporting documentation.

<table>
<thead>
<tr>
<th>Quality of Research</th>
<th>Minimum requirement</th>
<th>Documentation</th>
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<td>1. Intervention has produced one or more positive behavioral outcomes (p \leq .05) in mental health, mental disorders, substance abuse, or substance use disorders among individuals, communities, or populations.</td>
<td>A list of significant behavioral outcomes that includes supporting citations (document/page number) for each outcome; and</td>
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<td>2. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design.</td>
<td>A full-text copy of each article/report cited in the list of outcomes. Other research articles, published or unpublished evaluation reports, grant final reports, and replication studies may be submitted as additional supporting documentation.</td>
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<td>3. Results of these studies have been published in a peer-reviewed journal or other publication or documented in a comprehensive evaluation report.</td>
<td>Note: Abstracts or URLs to partial articles are regarded as incomplete and will not be considered.</td>
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TABLE 1—DOCUMENTATION FOR DEMONSTRATING COMPLIANCE WITH MINIMUM REQUIREMENTS

<table>
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<tr>
<th>Readiness for Dissemination</th>
<th>Minimum requirement</th>
<th>Documentation</th>
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<td>4. Implementation materials, training and support resources, and quality assurance procedures have been developed and are ready for use by the public.</td>
<td>A brief narrative description and list of available materials, resources, and systems to support implementation (e.g., treatment manuals, information for administrators, tested training curricula, mechanisms for ongoing supervision and consultation, protocols for gathering process and outcome data, ongoing monitoring of intervention fidelity, processes for gathering feedback); and</td>
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A brief description of the method through which new implementation sites acquire the above materials.

The following types of interventions are not eligible for review and should not be submitted to NREPP:
1. Stand-alone pharmacologic treatments—The evidence base for pharmacologic treatments is reviewed and approved through the U.S. Food and Drug Administration (FDA). FDA-approved pharmacotherapy interventions (on-label use) are considered for NREPP review only when combined with one or more behavioral or psychosocial treatments.
2. To remain consistent with SAMHSA’s mission (“to reduce the impact of substance abuse and mental illness on American communities”), NREPP will not accept for review, or otherwise include on the NREPP Web site, any interventions that have been developed or evaluated with funds or other support—either partially or wholly—from organizations whose goals or activities are determined to be inconsistent with SAMHSA’s mission.

Selection of Interventions for Review
All submissions meeting the minimum requirements will be considered eligible for review. In selecting interventions for review, SAMHSA may choose to give special consideration to interventions that meet one or more of the following conditions:
• The original investigator(s) or an independent party has used the same protocol with an identical or similar target population, and/or has used a slightly modified protocol based on a slightly modified population, where results are consistent with positive findings from the original evaluation.
• Implementation materials (e.g., program manuals, training guides, measurement instruments, implementation fidelity guides) are available to the public at no cost.
• The intervention targets underserved populations (e.g., minority populations, elderly, young adults, individuals who are incarcerated).
• The intervention contributes to a content area where there are currently limited evidence-based interventions.

Interventions that are not selected for review may be resubmitted by the applicant in a future open submission period.
Instructions for Submitting an Intervention

To submit an intervention, individuals should send a written statement to NREPP expressing their interest along with documentation that demonstrates the intervention meets the minimum requirements as described above. All submissions must be made either by a principal investigator (PI) who has conducted research on the intervention, a project director (PD) who has worked with an evaluator of the intervention, or a formally authorized delegate of the PI or PD. For information on where to submit materials, please call 1–866–436–7377. Electronic submissions are preferred, but materials may be sent to NREPP in hard copy via postal mail or fax. To be eligible for consideration, submissions must be received no later than 11:59 p.m. E.S.T. on February 1, 2012; those received before November 1, 2011, will be disregarded.

For each intervention that is accepted, the Principal (the individual, usually the PI, formally designated as the intervention’s point of contact and decisionmaking authority during the review process) will be asked to submit additional documentation to be used in the review. This additional documentation includes full-text copies of all articles and reports that provide evidence of significant outcomes (p ≤ .05) as well as copies of selected dissemination materials in the format they are provided to the public (e.g., hard copy or electronic versions of manuals, training presentations, tools, quality assurance protocols; URLs for interactive Web-based resources).

The Principal continues to work with NREPP staff throughout the review and is responsible for approval of the final intervention summary that is developed by NREPP staff once the review has been completed.

Contact Information

Individuals who have questions about the information contained in this notice may write to NREPP staff at nrepp@samhsa.hhs.gov or call 1–866–436–7377.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

Correction: This notice was published in the Federal Register on September 8, 2011, Volume 76, Number 174, Page 55678. The correct time should be 1 p.m.–3:30 p.m.

Contact Person for More Information:
Drue Barrett, Ph.D., Designated Federal Officer, ACD, CDC—ES, CDC, 1600 Clifton Road, NE., M/S D–50, Atlanta, Georgia 30333. Telephone (404) 639–4690. E-mail: dbbarrett@cdc.gov

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 12, 2011.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.