

complete coat that aids in survival in the intestine and environment.

The proposed use of general criteria for designating strains of *E. coli* as risk group 1 agents is not intended to eliminate the need for case-by-case consideration of the potential effects of a biological agent on those who may be exposed to it (Section II-A-2 of the NIH Guidelines) and any general criteria will be subject to reevaluation and change in light of evidence that a strain meeting those criteria is associated with disease in healthy adult humans.

Proposed Amendments to the NIH Guidelines

For the reasons stated above, it is proposed to amend Appendix B-I, Risk Group (RG1) Agents, to state:

Appendix B-I. Risk Group (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis* (see Appendix C-IV-A, *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems, Exceptions); adeno-associated virus (AAV) types 1 through 4; and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of *Escherichia coli* (see Appendix C-II-A, *Escherichia coli* K-12 Host Vector Systems, Exceptions) is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (i.e., lacks the O antigen and has a "rough" colony morphology); and (2) does not carry any active virulence factor (e.g., toxins) or colonization factors and does not carry any genes encoding these factors.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

Dated: August 3, 2001.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Continuation of the Cooperative Agreement for the State Treatment Outcomes and Performance Pilot Studies Enhancement Technical Assistance Center

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

ACTION: Continuation of the cooperative agreement with the State Treatment Outcomes and Performance Pilot Studies Enhancement Technical Assistance Center Grantee, Johnson, Bassin and Shaw, Incorporated, for one year.

SUMMARY: This notice is to inform the public of the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment's (CSAT) planned award to Johnson, Bassin and Shaw (JBS), Inc., to continue to serve as the Technical Assistance Center for the State Treatment Outcomes and Performance Pilot Studies Enhancement (TOPPS II) cooperative agreement program for one year. An additional year of support is needed to provide detailed statistical analyses of the final data set, to develop comprehensive written reports laying out the complete final analyses and results, and to translate the results into written and oral forms that can be understood and used by the substance abuse treatment field. In fiscal year 2001, CSAT plans to make approximately \$380,000 available for the award to JBS, Inc. The award will be made if the application is scored by the initial review group and concurred with by the CSAT National Advisory Council.

Eligibility for the cooperative agreement is limited to JBS, Inc., Only JBS, Inc., may apply because they have served as the Technical Assistance Center for the multi-site study during the past 2+ years of data collection. They developed the necessary infrastructure for the collection, analysis and dissemination of TOPPS II project data, and have experience working with the current 16 TOPPS II single State agency grantees. JBS, Inc., designed and maintains the TOPPS II database, collects and cleans the grantees' admission and discharge data, and is currently receiving and processing follow-up data. It would be an impediment to the orderly conduct of the study if there were a disruption in

data collection and analyses. JBS, Inc., has hired competent and capable staff with experience in conducting large, prospective, multi-site, substance abuse services performance and outcome studies. The incumbent works collaboratively with Federal and State staff, and members of the TOPPS II Steering Committee to facilitate the development of the TOPPS II data collection protocols, and to develop instruments and protocols for performance and outcome measurement, data quality management, secondary data analysis, statistical analysis and technical report writing.

Because of the incumbent's experience with this initiative, JBS, Inc., is uniquely positioned to guide the overall effort and to integrate the work of the TOPPS II study sites into a conceptual whole. To compete this announcement otherwise, would be duplicative and inefficient. Therefore, the eligibility for a continuation cooperative agreement with SAMHSA/CSAT is being limited to the incumbent, JBS, Inc.

Authority: The cooperative agreement with JBS, Inc., will be made under the authority of section 1935 (b)(1)(C) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.238.

CONTACT: Hal Krause, CSAT, SAMHSA, Rockwall II, Suite 880, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-0488; e-mail: hkrause@samhsa.gov.

Dated: August 7, 2001.

Richard Kopanda,
Executive Officer, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2002 Funding Opportunities

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

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, A Cooperative