(1) FDA's letters to BRC dated July 8, 1998, January 21, 1999, and November 3, 2000; and (2) BRC's response to FDA dated July 30, 1998. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

BRC may submit to the Dockets Management Branch (see **ADDRESSES**) a written request for a hearing by June 10, 2002, and any data and information justifying a hearing must be submitted by July 8, 2002. Other interested persons may submit written comments on the proposed license revocation to the Dockets Management Branch by July 8, 2002. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If the Commissioner of the Food and Drugs (the Commissioner) determines upon review of any objections or request for a hearing that a hearing is not justified, in whole or in part, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner will deny the hearing request, with an explanation for the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: May 2, 2002.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 02–11509 Filed 5–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Extramural Support Program for Projects To Increase Organ Procurement

AGENCY: Health Resources and Services Administration, Health and Human Services.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2002 funds to be awarded under the Division of Transplantation (DoT) program for discretionary grants, under a new competition that supports the evaluation of clinical interventions to increase the number of heart-beating and non-heart-beating organ donors and/or the number of organs that could be recovered from such donors. In concert with HHS' Gift of Life Donation Initiative, this extramural program, Clinical Interventions to Increase Organ Procurement, will fund grants of up to 3 years duration to implement, evaluate, and disseminate model interventions with the greatest potential for yielding a verifiable and demonstrable impact on organ procurement and which are replicable, transferable, and feasible in practice. Applicants must be qualified organ procurement organizations (OPOs) or other nonprofit private organizations actively involved in the field of transplantation. Strong evaluation project components and staffing expertise are required.

Authority for this program is provided by section 371(a)(3) of the Public Health Service (PHS) Act, 42 U.S.C. 273(a)(3), as amended.

DATES: To help HRSA adequately plan for the Objective Review Process, Letters of Intent are encouraged from all applicants. Such letters should be sent to: Lynn Rothberg Wegman, M.P.A., Director, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Land, Room 7C–22, Rockville, Maryland 20857, or faxed to: 301/594–6095 or 301/443–1267. Such letters should be received by DoT by June 10, 2002. Receipt of these notices of intent will not be routinely acknowledged.

EFFECTIVE DATE: Applications must be received in the HRS Grant Application Center by the close of business July 8, 2002, to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted instead of a postmark. Private metered postmarks shall not be accepted as proof of timely mailing. Applications postmarked after the deadline will be returned to the applicant.

ADDRESSES: The official grant application kit and guidance materials for this announcement may be obtained on the following three web sites: *www.hrsa.gov*, *www.hrsa.gov/osp/dot/*, and *www.organdonor.gov*, and from the HRSA Grants Application Center, Attn: CFDA 93.134; 2002 Clinical Interventions to Increase Organ Procurement, The Legin Group, Inc., 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879; telephone 877/477–2123, e-mail address *hrsagac@hrsa.gov.* Applicants are strongly advised to obtain the Guidance before preparing applications. Applicants for grants will use Revised Form PHS 5161–1. This form may be downloaded from the DHHS Program Support Center (PSC) website at: *http://www.psc.gov/forms/PHS/phs.html.* The application guidance may be accessed through HRSA's website at *www.hrsa.gov/grants.htm.*

FOR FURTHER INFORMATION CONTACT: Additional information regarding business, administrative, and fiscal issues related to the awarding of grants under this Notice may be requested from Darren S. Buckner, Grants Management Specialist, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Land, Room 7–89, Rockville, MD 20857; telephone 301/443–1913; fax 301/594–6096; e-mail address *DBuckner@hrsa.gov.*

Additional information regarding program issues and the overall Program may be requested from Laura M. Saint Martin, M.D., M.P.H., Medical Officer, or Virginia McBride, R.N., B.S., CPTC, Public Health Analyst, Operations and Analysis Branch, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Land, Room 7C–22, Rockville, MD 20857; telephone number 301/443–

7577; fax 301/594–6095 or 301/443–1267. Dr. Saint Martin can be reached via e-mail at *LStMartin@hrsa.gov*; Ms. McBride can be reached at *VMcBride@hrsa.gov.*

Technical assistance regarding this funding announcement may be requested from Virginia McBride, R.N., B.S., CPTC, Public Health Analyst, Operations and Analysis Branch, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Room 7C–22, Rockville, MD 20857; fax 301/594–6095 or 301/443–1267; e-mail address *VMcBride@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Purposes

Organ donation has become an increasingly important public health issue. Only about 6,000 deaths in the United States each year result in organ donation, compared with an estimated potential of 8,000–15,000 donors. Moreover, nearly 80,000 patients are currently awaiting transplants and about 5,500 patients die each year because of the critical shortage of transplantable organs.

In September 1999, HRSA's Division of Transplantation (DoT) instituted its Model Interventions to Increase Donation grant program that focused on interventions to increase cadaveric organ and tissue donation. In 2001, the program was expanded to include interventions to increase living donation and the development of hospital donor protocols and educational interventions to increase non-heart-beating donation. To be considered eligible, interventions must be intended to increase organ procurement, raise consent rates for organ donation, and/or increase the rate of declaration of intent to donate coupled with family notification of intent to become an organ donor.

To date, interventions funded by DoT's grant program that address the first criterion, increasing organ procurement, have focused on improving hospital and OPO interactions/practices to identify donors and provide emotional support to donor families. However, additional opportunities to increase the rate of organ procurement exist but continue to fall outside the scope of HRSA's current grant program. In fact, many interventions that would likely increase organ procurement efficiency do not appear to qualify for any HHS funding opportunities possibly because the research would need to be conducted after pronouncement of a donor's death.

For this reason, DoT is proposing the development of a new grant program, Clinical Interventions to Increase Organ Procurement, to support the evaluation of clinical interventions to increase the number of heart-beating and non-heart-beating organ donors and/or the number of organs that could be recovered from such organ donors. Eligible interventions could focus on new and/or improved methods to optimize hemodynamic stability in brain dead patients, improve donor organs with compatible recipients. Additionally, projects leading to more accurate identification of appropriate non-hear-beating donation candidates and improved methods of donor stabilization and organ recovery would qualify. Improving OPO internal processes, such as improved quality assurance practices, also would be acceptable if it can be demonstrated that these efforts result in increased organ procurement.

This grant program is focused solely on clinical interventions to increase heart-beating and non-heart-beating cadaveric donation. Funds will not be used for other types of projects. Examples of research that will *not* be supported under this program are: Living donation; clinical trials of drugs not approved by the FDA or off-label uses of FDA-approved drugs; research involving animals; long-term transplantation outcomes research; interventions to increase tissue donation alone; practices related to the pronouncement of death; and interventions inconsistent with Federal law or statute. Projects falling within the scope of DoT's grant program, Model Interventions to Increase Organ and Tissue Donation, also are not eligible to receive funding under the clinical interventions program.

Projects can employ qualitative studies, quantitative research, or empiric work. As emphasized during the April 1–2, 1998, national conference titled ''Increasing Donation and Transplantation: The Challenge of Evaluation'' sponsored by HHS' Office of the Assistant Secretary for Planning and Evaluation with additional support provided by the Agency for Healthcare Research and Quality and the National Institute of Allergy and Infectious Diseases, HHS places a high priority on research and evaluation. HHS has served, and plans to continue to serve, as a catalyst for the field by emphasizing and encouraging carefully designed and rigorous evaluation components and research projects to ascertain effective interventions for increasing donation and procurement.

Review Criteria

The review of applications will take into consideration the proposed criteria listed below. The system for scoring each application will range from 0–100 points, with 100 being best.

1. (30 points) Potential of the project to yield a demonstrable and verifiable impact on organ procurement.
2. (25 points) Degree of scientific rigor in the design, implementation, and evaluation of the project.
3. (20 points) Experience and expertise of proposed project staff as supported by education, relevant publications and work history.
4. (15 points) Extent to which projects are replicable, transferable, and practical.
5. (10 points) Adequacy of facilities, resources, and collaborative arrangements relevant to the goals of the project.

Performance Measures

All project must include rigorous outcome evaluation protocols. Outcomes and performance measures must be identified and defined to determine effectiveness of the project. Performance measures are expected to address one or more of the following outcomes:

1. Organ donation rates;
2. Organ procurement rates; and/or
3. Organ transplant rates.

Availability of Funds: The Clinical Interventions to Increase Organ Procurement Program is authorized by Section 371(a)(3) of the Public Health Service (PHS) Act, 42 U.S.C. 273(a)(3), as amended. This section authorizes the Secretary to make grants to qualified organizations for the purpose of carrying out special projects designed to increase the number of organ donors.

HRSA expects to award under this program up to $3 million in FY2002 to support the first year of approximately 12–20 projects. Subsequent years' funding depends on the availability of appropriations, program priorities, and recipient performance. Projects will be awarded for up to 3 years. The budget and project periods for approved and funded projects will begin on or about September 30, 2002. All applicants should submit budgets for the three-year period.

Eligible Applicants: The proposed project may be conducted solely by an OPO or by a consortium of relevant entities or organizations, of which one organizational member (the applicant) carries overall responsibility for project leadership and administration of the HRSA grant award. The applicant must be a Federally designated OPO (section

1138(b) of the Social Security Act) or other nonprofit private organization actively involved in the field of transplantation, or a Federal institution in accordance with section 235 of the Public Health Service Act. If the consortium approach is used, members and roles must be identified in the application and all members must have substantive involvement in the project. For-profit organizations may participate as members of consortia, but not as the applicant.

The OMB Catalog of Federal Domestic Assistance number for the Clinical Interventions to Increase Organ Procurement Program is 93.134.

Paperwork Reduction Act: OMB approval for any data collection in connection with these grants will be sought, as required under the Paperwork Reduction Act of 1995.

Dated: April 19, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–11580 Filed 5–8–02; 8:45 am]

BILLING CODE 4165–15–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Assessment of the Use of Special Funding for Research on Type 1 Diabetes Provided by the Balanced Budged Act of 1997 and the FY 2001 Consolidated Appropriations Act.

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 28, 2001, page 59438 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Assessment of the Use of Special Funding for Research on Type 1 Diabetes Provided by the Balanced Budget Act of 1997 and the FY 2001 Consolidated Appropriations Act. *Type of Information Collection Requested:* NEW. *Need and Use of Information Collection:* This survey will be one source of input into a statutorily mandated assessment and report to the Congress on special funding for research on type 1 diabetes provided by 42 U.S.C. 254c–2 and 42 U.S.C. 1254c–2 note, ''Special Diabetes Program for Type 1 Diabetes'' (as created by the Balanced Budget Act of 1997, Pub. L. 105–33, and amended by the FY 2001 Consolidated Appropriations Act, Pub. L. 106–554). The primary objective of this study is to gain information, via a brief questionnaire, from NIH research grantees who were the primary recipients of these special funds. The responses will provide valuable information concerning how the funds have facilitated research as intended by these Acts of the Congress. Information from this study will aid in evaluation of the process by which the research goals for use of the special type 1 diabetes funds have been developed and are being pursued. Responses from this study will contribute to a statutorily mandated report, due to the Congress on January 1, 2003 (42 U.S.C. 254c–2 and 42 U.S.C. 1254c–2 note), evaluating the process and efforts under this program and assessing research initiatives funded by these Acts of the Congress. *Frequency of Response:* The initial survey will require a one time response; though, respondents may be contacted again in the event of future congressionally mandated reports on the use of the special type 1 diabetes research funds. *Affected Public:* Research scientists who received the special funds about which the Congress has mandated in law the requirements for an evaluation report. *Type of Respondents:* Laboratory and clinical investigators who have received support from the special type 1 diabetes funds provided under the laws previously cited. The annual reporting burden is as follows: *Estimated number of respondents:* 300; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 1 hour for nine questions; and *Estimated Total Burden Hours Requested:* 300. The annualized total cost to respondents is estimated at: $15,000. It is expected that the respondents will be contacted and will return their responses via electronic mail. These measures will reduce the burden on the respondents and the overall costs of administering the study. Respondents will be asked to answer nine questions, one-third of which will be answered with ''yes'' or ''no'' or a one-word response. There are no Capital Costs, Operating Costs or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information one those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Michelle A. Cissell, AAAS/NIH Science Policy Fellow, Office of Scientific Program and Policy Analysis, NIDDK, NIH, Building 31, Room 9A11, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–6623 or e-mail your request, including your address to: *cissellm@extra.niddk.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 22, 2002.

Barbara Merchant,

Executive Officer, NIDDK.

[FR Doc. 02–11521 Filed 5–8–02; 8:45 am]

BILLING CODE 4140–01–M