TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section/ FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.82(a)(9)	18	1	18	135	2,430
814.84(b)	648	1	648	10	6,480
Section 201 (FDAMA) Agreement Meeting	3	1	3	50	150
Section 202 (FDAMA) Expedited Review Request	5	1	5	10	50
Section 205 (FDAMA) Effectiveness Meeting	5	1	5	50	250
Section 208 (FDAMA) Classification Panel Meetings	20	1	20	30	600
Section 209 (FDAMA) 100-day meeting	28	1	28	10	280
Totals	2,050	13	2,050	1,214	89,004

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.82(a)(5) and (a)(6)	698	1	698	17	11,866

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23912 Filed 9–23–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ANA Consultant and Evaluator Qualifications Form.

OMB No.: 0970–0265.

Description: The ANA Consultant and Evaluator Qualifications Form is used to collect information from prospective proposal reviewers in compliance with 42 U.S.C. 2991d–1. The form allows the Commissioner of ANA to select qualified people to review grant applications for Social and Economic Development Strategies (SEDS), Native Language Preservation and Maintenance, and Environmental Regulatory Enhancement. The panel review process is a legislative mandate in the ANA grant funding process.

Respondents: Native Americans, Native Alaskans, Native Hawaiians and other Pacific Islanders.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Consultant and Evaluator Qualifications Form	300	1	1	300

Estimated Total Annual Burden Hours: 300.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 21, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–23923 Filed 9–23–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Donor Management Research: Improvements in Clinical Management of Deceased Organ Donors

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for information.

SUMMARY: The Health Resources and Services Administration (HRSA), Division of Transplantation, is soliciting input, feedback, and suggestions from researchers and interested parties within the organ donation and transplant community regarding guidance for a possible grant or contract that focuses on improvements in clinical management of deceased organ donors.

Given the continued imbalance between the demand for and supply of deceased donor organs, it is essential that deceased donors be managed appropriately to optimize the number and function of donor organs. It is reasonable to expect that better clinical donor management would improve organ quality, organs transplanted per donor (OTPD), and post-transplant recipient outcomes.

DATES: Written or electronic comments must be received by HRSA by October 15, 2010.

ADDRESSES: Please send all written comments to James Bowman, MD Medical Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Suite 12C–06, Rockville, Maryland 20857; Telephone (301) 443–4861 Fax (301) 594–6095; or e-mail: *jbowman@hrsa.gov.*

Docket: For access to the docket to view comments received, phone 301–443–7577 to schedule an appointment to view public comments.

FOR FURTHER INFORMATION CONTACT: James Bowman, MD, Medical Director at Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, at the contact information cited above.

SUPPLEMENTARY INFORMATION:

Background

Since 2002, HRSA has funded the Clinical Interventions to Increase Organ Procurement (CIOP) Grant Program, authorized by Public Health Service Act, as amended, Section 377A(b), (42 U.S.C. 274f–1). The CIOP Grant Program has provided support for the implementation and evaluation of highly promising strategies and approaches serving as model interventions for identifying appropriate organ donor candidates, evaluating donated organs, maintaining donor clinical stability and optimizing methods for organ procurement. Other than the fiscal year 2007 CIOP grant cycle, which focused on uncontrolled donation after circulatory death donors, the CIOP Program has not focused on specific research issues. Since the inception of the grant program, 19 grants have been awarded. While these grants have furthered knowledge regarding clinical management of donors, the studies have generally focused on specific organ systems and not on donor management approaches with the goal of optimizing all organ systems.

The CIOP Grant Program was not funded in Fiscal Year 2010 to allow HRSA to consider how to best utilize the limited Federal research funds available in a more useful and beneficial manner. There has been considerable discussion among critical care and transplant specialists regarding donor management. A Donor Management Task Force was convened in August 2010 to address relevant issues in donor management practices. This task force discussed: (1) Advancing the scientific knowledge that influences organ donor management practices; (2) promoting the adoption of critical care and quality improvement practices in each Donation Service area (DSA) that optimize organ viability and increase OTPD; (3) ensuring that all patients meeting the neurologic criteria for determination of death are pronounced in a timely manner so that organ donation intentions may be fully honored; and (4) ensuring that each donation case occurs using the most appropriate donation pathway: Either donation after neurologic determination of death or donation after cardiac determination of death. Although quality donor management may be assumed to improve transplantation outcomes, there are limited scientifically rigorous studies validating this assumption. The studies that do exist involve a limited number of DSAs. These studies do suggest an improvement in OTPD based on certain donor management practices, but further investigation is needed. Upon review of research possibilities being discussed in meetings and in the literature, HRSA believes that research should be directed to help establish evidence-based donor management protocols.

Therefore HRSA is considering funding through a grant or contract mechanism to one or two parties, a total of up to $1 million/year for three (3) years to conduct a multicenter, nationwide study focused on donor management and improvement in outcomes, particularly OTPD, organ quality, and post-transplant recipient outcomes.

Request for Comments

For this Request for Information, respondents are asked to present their experiences and opinions regarding the importance of further study into donor management and its outcomes. Suggestions and comments concerning specific areas of analysis are encouraged. Such studies might consider developing or refining a validated tool useful for predicting donor outcomes based upon appropriate and readily available donor data (*e.g.,* collected for purposes of OPTN data submission, or routinely collected by Organ Procurement Organizations). Donor management study designs that include OPTN data collected on most, if not all, deceased donor organs will be encouraged.

HRSA is seeking guidance from the community to help structure either a donor management study to be accomplished by contract or targeted research questions that will be incorporated into the CIOP FY 2011 request for application.

Dated: September 16, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–23893 Filed 9–23–10; 8:45 am]

BILLING CODE 4165–15–P