

4. 402(j)(3)(A)(ii)(II), 42 U.S.C. 282(j)(3)(A)(ii)(II): To ensure that the Data Bank includes links to specified NIH information.

5. 402(j)(3)(A)(ii)(iii), 42 U.S.C. 282(j)(3)(A)(ii)(iii): To include links to the FDA and NIH information described above for Data Bank entries for clinical trials submitted to the Data Bank prior to the enactment of FDAAA.

6. 402(j)(3)(C), 42 U.S.C. 282(j)(3)(C): To include in the Data Bank the specified "basic results" information for drugs that are approved under section 505 of the Federal Food, Drug and Cosmetic Act or licensed under section 351 of the Public Health Service Act, and for devices that are cleared under section 510(k) of the Federal Food, Drug and Cosmetic Act, or approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act.

7. 402(j)(3)(D)(vi), 42 U.S.C. 282(j)(3)(D)(vi): To consider the status of World Health Organization consensus data elements for reporting clinical trial results when issuing regulations.

8. 402(j)(3)(D)(vii), 42 U.S.C. 282(j)(3)(D)(vii): To hold a public meeting to provide an opportunity for input from interested parties with regard to the regulations to be issued pursuant to 42 U.S.C. 282(j)(3)(D)(i).

9. 402(j)(3)(I)(iii), 42 U.S.C. 282(j)(3)(I)(iii): To include in the Data Bank tables of information of anticipated and unanticipated serious adverse events and anticipated and unanticipated frequent adverse events, upon the application of 42 U.S.C. 282(j)(3)(I)(ii).

10. 402(j)(3)(I)(iv), 42 U.S.C. 282(j)(3)(I)(iv): To consult with experts in risk communication and post, with the tables described in 42 U.S.C. 282(j)(3)(I)(iii), information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

11. 402(j)(4)(B)(i), 42 U.S.C. 282(j)(4)(B)(i): To determine for a specified clinical trial, that posting in the Data Bank of clinical trial information for such clinical trial is necessary to protect the public health, and further, to require by notification that such information be submitted to, and accepted on behalf of the Secretary by, the Director of the National Institutes of Health, in accord with 42 U.S.C. 282(j)(4)(B)(i)(I).

12. 402(j)(5)(A)(iv), 42 U.S.C. 282(j)(5)(A)(iv): To consult with other agencies that conduct human subjects research in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulation), to determine if such research is an applicable clinical trial and develop, with such agencies,

procedures to ensure the submission of clinical trial information.

13. 402(j)(5)(C)(i), 42 U.S.C. 282(j)(5)(C)(i): To use the publicly available information and any other information available to the Secretary about applicable clinical trials to verify the accuracy of submitted results information for the Pilot Quality Control Study.

This delegation will be exercised in accordance with the Department's applicable policies, procedures, guidelines and regulations.

I ratify and affirm any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of this delegation. This delegation is effective upon date of signature.

Dated: April 21, 2009.

Charles E. Johnson,

Acting Secretary.

[FR Doc. E9-9699 Filed 4-29-09; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Reservation Roads

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission of information collection to the Office of Management and Budget.

SUMMARY: The Bureau of Indian Affairs (BIA) is submitting the information collection for the Indian Reservation Roads (IRR) Program, OMB Control No. 1076-0161, to the Office of Management and Budget for renewal. The current approval period is approaching expiration; this renewal will allow us to continue to operate the IRR program. This renewal is necessary for tribal participation in the IRR Program and for the allocation of funding for the IRR Program to federally recognized tribal governments for transportation assistance.

DATE: Submit comments on or before June 1, 2009.

ADDRESSES: Submit comments on the information collection to the Desk Officer for the Department of the Interior at the Office of Management and Budget, by fax at (202) 395-5806 or e-mail at OIRA_DOCKET@omb.eop.gov. Please send copy of your comments to: LeRoy Gishi, Chief, Division of Transportation, 1849 C Street, NW, MS 4512 MIB, Washington, DC 20240, fax: (202) 208-4696.

FOR FURTHER INFORMATION CONTACT: You may request further information or obtain copies of the proposed information collection request from LeRoy Gishi, Chief, Division of Transportation, telephone (202) 513-7711.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection is necessary to allow Federally recognized tribal governments to participate in the IRR Program as defined in 23 U.S.C. 204(a)(1). Some of the information collected determines the allocation of IRR program funds to Indian tribes as described in 23 U.S.C. 202(d)(2)(A).

II. Summary of Public Comments Received

The BIA received comments from one commenter in response to the notice published January 12, 2009 (74 FR 1244), which announced that we would submit this renewal to OMB for approval and provided the 60-day public comment period. The commenter had a number of suggestions that would be appropriate for consideration upon amending the rule; however, because the scope of this public comment period is limited to the information collections, the BIA was not able to accommodate these requests. Comments specific to the information collection included the following. The commenter expressed concern that the word "some" in the Brief Description indicated that there were other information collections that BIA did not address. The Brief Description addresses all the information collections associated with Indian Reservation Roads—the word "some" indicates that some of these information collections are required to obtain or maintain a benefit (program participation and funding) and others are voluntary. Another comment asked why an applicant must provide documentation that the project meets the definition of an IRR transportation facility and is on the IRR inventory when the information already exists. The BIA requires this information as part of the IRR High Priority Project application because the application is a collection of all information necessary for the Department to make an approval determination based upon criteria established by law. The commenter also stated that they believe that the amount of information could be reduced. The information collection was developed by meetings between tribal members and the BIA. What emerged was a list that met the various needs of the tribe and the requirements of the law which

authorizes the funding for IRR. While the list is long, those data elements can also be helpful to tribes who coordinate projects and transportation activities with other public authorities. It is not all required to be provided in order to participate in the program; that is the reason for default values in the CFR tables. The commenter stated that there is a difference in requested items from region to region because of politics and physical roadway characteristics, and questioned the practical utility of some requested information, suggesting a committee evaluate the need further since not all requested information is listed in the CFR. The BIA participated in many meetings of committees and public hearings when the requirements were developed—the result was a list of requirements that covered all situations, but not necessarily all requirements are needed for each situation. The commenter also stated that too much information is required in certain instances. The BIA has determined that, in those instances, the additional data are beneficial in supporting more accurate decisions rather than using default tables and that it is beneficial to the tribe to include this information. The commenter stated that they believe that the time and cost of submitting certain information far exceeds their estimated amount. The time and cost associated with data collection and submission has been consistently decreasing in the three years prior to this request for comment as improved methods of collection are developed. The estimated time and cost of submitting data indicates that the commenters are increasingly successful in assuring that data are provided for purposes identified. Finally, the commenter stated that use of automated techniques does not abrogate the physical collection of data and that a technological solution may be available with funds for equipment and staff to maintain the automated equipment. In response, the BIA notes that no special equipment is necessary for this information collection, and that more advanced techniques are available but this collection process does not require their use. The BIA did not make any changes to the information collection request for approval in response to these comments.

III. Request for Comments

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the

agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the commenters, such as through the use of automated collection techniques or other forms of information technology.

Please note that an agency may not sponsor or request, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number. OMB has up to 60 days to make a decision on the submission for renewal, but may make the decision after 30 days. Therefore, to receive the best consideration of your comments, you should submit them closer to 30 days than 60 days.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section, room 4516 MIB, during the hours of 8 a.m.–4:30 p.m., EST Monday through Friday except for legal holidays. Before including your address, phone number, e-mail address or other personally identifiable information, be advised that your entire comment—including your personally identifiable information—may be made public at any time. While you may request that we withhold your personally identifiable information, we cannot guarantee that we will be able to do so. All comments from organizations or representatives will be available for review. We may withhold comments from review for other reasons.

IV. Data

OMB Approval Number: 1076–0161.

Title: 25 CFR 170, Indian Reservation Roads.

Brief Description of Collection: Some of the information such as the application of Indian Reservation Roads High Priority Projects (IRRHPP) (25 CFR 170.210), the road inventory updates (25 CFR 170.443), the development of a long range transportation plan (25 CFR 170.411 and 170.412), the development of a tribal transportation improvement program and priority list (25 CFR 170.420 and 170.421) are required to maintain or obtain a benefit (consideration of projects and for program funding from the formula). Some of the information such as public hearing requirements are also required to maintain or obtain a benefit and provides public notification and the opportunity for public involvement (25 CFR 170.437 and 170.439). While others such as data appeals (25 CFR 170.231)

and requests for design exceptions (25 CFR 170.456) are voluntary information.

Type of Review: Renewal.

Respondents: Respondents include Federally recognized Indian tribal governments who have transportation needs associated with the IRR Program as described in 25 CFR 170.

Number of Respondents: Varies from 10 to 281.

Estimated Time per Response: The reports require from 30 minutes to 40 hours to complete. An average would be 16 hours.

Frequency of Response: Annually or on an as needed basis.

Total Annual Burden to Respondents: 19,628 hours.

Total Annual Cost to Respondents: \$0.

Dated: April 24, 2009.

Sanjeev “Sonny” Bhagowalia,

Chief Information Officer—DOI.

[FR Doc. E9–9921 Filed 4–29–09; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–NWRS–2009–N0016;1265–0000–10137–S3]

McNary and Umatilla National Wildlife Refuges, Benton, Walla Walla, and Franklin Counties, WA, and Morrow and Umatilla Counties, OR

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of the final comprehensive conservation plan, environmental assessment, and finding of no significant impact.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have completed a comprehensive conservation plan, environmental assessment (CCP/EA), and finding of no significant impact (FONSI) for the McNary and Umatilla National Wildlife Refuges (Refuges), which are part of the Mid-Columbia River National Wildlife Refuge Complex (Complex). The CCP/EA was developed to provide a foundation for the management and use of the Refuges. We are furnishing this notice to advise other agencies and the public of the availability of the CCP/EA and FONSI, and the decision to implement Alternative 2 as described in the CCP/EA. The Service's Regional Director for the Pacific Region selected Alternative 2 for managing the Refuges for the next 15 years. The Refuges are located along the Columbia River in the states of Oregon and Washington.