

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Community Living****Agency Information Collection Activities; Proposed Collection; Comment Request; Older Americans Act, Title VI Grant Application**

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed extension without change information collection and solicits comments on the information collection requirements related to the Application for Older Americans Act, Title VI Parts A/B and C Grants.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by June 7, 2022.

**ADDRESSES:** Submit electronic comments on the collection of information to: Jasmine Aplin. Submit written comments on the collection of information to the Administration for Community Living, Washington, DC 20201, Attention: Jasmine Aplin.

**FOR FURTHER INFORMATION CONTACT:** Jasmine Aplin, Administration for Community Living, Washington, DC 20201, [jasmine.aplin@acl.hhs.gov](mailto:jasmine.aplin@acl.hhs.gov) or 202-795-7453.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A

Collection of information includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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 on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

ACL is responsible for administering the Title VI A/B (Nutrition and Supportive Service) and C (Caregiver) grants. The purpose of this data collection is to improve and standardize the format of the application. The instrument will collect data as prescribed by the Older Americans Act Section 612(a), 614(a) and 45 CFR 1326.19 related to the eligibility of Federally-recognized Tribes and Native Hawaiian organizations for grant funds under this program and their capacity to deliver services to elders.

The Application for Older Americans Act, Title VI A/B and C Grants collects information on the ability of federally-

recognized American Indian, Alaskan Native and Native Hawaiian organizations to provide nutrition, supportive, and caregiver services to elders within their service area. Applicants are required to provide a description of their organization's service area, the number of eligible elders in their service area, and their ability to deliver services and sign assurances that the organization will comply with all applicable laws and regulations.

This is an extension of a currently approved information collection. The proposed data collection materials have been updated to better align with the requirements of the Older Americans Act and Federal regulations, as well as to improve data quality and grantee accountability. Furthermore, this grantee application will better line up with the Title VI Program Performance Report under 0985-0059. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRMA).

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

**Estimated Program Burden**

Title VI funding is broken into three categories. Parts A and B are for nutritional and supportive programming, with Part A being restricted to American Indian and Alaska Native grantees, and Part B restricted to Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B funding, but not all Part A/B grantees will have Part C programs. Therefore, there are likely to be 295 unique respondents, but only 250 will have to complete all three portions of the application. This application covers all three parts of Title VI.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Application Part A/B .....	295	1	2.75	270.4
Title VI Application Part C .....	250	1	1.5	125
Total .....	.....	.....	4.25	395.4

The number of burden hours associated with the Title VI, Part C, data

collection was calculated as 811.25. However, since this instrument is used

only once every three years results in an annualized number of 270.4 hours.

Similarly, the total hours associated with the Title VI, Part C, application is 375.

Dated: April 4, 2022.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-D-1268]

#### Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.” When final, this guidance will represent FDA’s current thinking on the use of whole slide images during good laboratory practice (GLP)-compliant toxicology studies using non-human specimens. When whole slide images are used as part of a nonclinical study conducted in compliance with the GLP regulations, adequate documentation is critical. Documentation practices during generation, use, and retention of whole slide images have not been clearly defined and vary among nonclinical testing facilities. This question-and-answer document is intended to clarify FDA’s recommendations concerning the management, documentation, and use of whole slide images in histopathology assessment and/or pathology peer review for nonclinical studies conducted in compliance with the GLP regulations.

**DATES:** Submit either electronic or written comments on the draft guidance by June 7, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2021-D-1268 for “Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Tahseen Mirza, Office of Study Integrity and Surveillance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993, 301-796-7645; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911; Judy Davis, Office of Device Evaluation, Center for Devices and