

PICOTSS (populations, interventions, comparators, outcomes, timing, settings, study designs) PICOTSS	Inclusion	Exclusion
Timing Setting(s) Study design and other limiters	<p>GQ3:</p> <ul style="list-style-type: none"> Strategies will be documented regardless of any information on outcome effects, but strategies need to aim to prevent, reduce, or mitigate disparities and barriers to survivorship care. <p>GQ4:</p> <ul style="list-style-type: none"> Changes (reduction) in disparities between comparison groups for outcomes listed in GQ1 and GQ2. <p>GQ5:</p> <ul style="list-style-type: none"> Ongoing and upcoming studies need to indicate that the study will report on outcomes eligible for GQ1, GQ2, or GQ4. <p>All GQs:</p> <ul style="list-style-type: none"> No timing restriction apply. Studies may address CCS who recently or long in the past experienced pediatric cancer and are now in remission. <p>All GQs:</p> <ul style="list-style-type: none"> All care settings applicable to US settings will be eligible, including primary, secondary, and tertiary care; inpatient and outpatient care; pediatric and adult care context. <p>All GQs:</p> <ul style="list-style-type: none"> English-language publications. <p>GQ1, GQ2, GQ4, GQ5:</p> <ul style="list-style-type: none"> Primary studies reporting empirical data (including both quantitative and qualitative data). <p>GQ1, GQ2:</p> <ul style="list-style-type: none"> Studies may either report on distinct subgroups, <i>e.g.</i>, dividing the sample by geographic characteristic and reporting data separately for rural and for urban participants or studies may report associations with participant characteristics, <i>e.g.</i>, reporting correlations with a factor of interest such as gender differences. <p>GQ3:</p> <ul style="list-style-type: none"> Strategies have to have been empirically tested in a research study reporting on the outcomes of interest or have been suggested by an authoritative source such as a clinical practice guideline or relevant professional organization. <p>GQ 4:</p> <ul style="list-style-type: none"> Studies with concurrent (<i>e.g.</i>, randomized controlled trial) or historic comparator (<i>e.g.</i>, organizational pre-post studies). Studies with results published in clinicaltrials.gov will be included regardless of whether a journal publication is available. <p>GQ5:</p> <ul style="list-style-type: none"> Ongoing and upcoming studies have to have a published protocol or are registered in a research registry. 	<p>All GQs:</p> <ul style="list-style-type: none"> No exclusions apply. <p>All GQs:</p> <ul style="list-style-type: none"> Studies in resource-limited settings such as developing countries will be reviewed for comparability with US settings. <p>All GQs:</p> <ul style="list-style-type: none"> Evaluations reported only in abbreviated format (<i>e.g.</i>, in a conference abstract) with the exception of trial records. Studies exclusively reported in non-English publications. Systematic reviews will be retained for reference mining but are not eligible for inclusion.

Dated: July 9, 2020.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2020-15190 Filed 7-14-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Title VI Program Performance Report (OMB 0985-0007)

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 the Proposed Revised Collection and solicits comments on the information collection requirements related to the extension of the Title VI Program Performance Report.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 14, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Leslie Green
Leslie.Green@acl.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Leslie Green, Administration for Community Living, *leslie.green@acl.hhs.gov*, 202–868–9384.

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 Program Performance Report. The purpose of this data collection is to fulfill the annual programmatic reporting required by the Title VI Part A/B and C grants to American Indians, Alaskan Native and Native Hawaiian Programs to provide nutrition, supportive services and caregiver services to elders and their caregivers.

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: There are 282 respondents taking 3.49 hours each to complete the response.

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 PPR	282	1	3.49	984
Total	984

Dated: July 8, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–15278 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2223]

Clinical Investigations for Prostate Tissue Ablation Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance entitled “Clinical Investigations for Prostate Tissue Ablation Devices.” This guidance provides recommendations for clinical investigations for high intensity ultrasound systems for prostate tissue ablation and new types of prostatic tissue ablation devices.

DATES: The announcement of the guidance is published in the **Federal Register** on July 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–2223 for “Clinical Investigations for Prostate Tissue Ablation Devices.” 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