Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Elaine Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2169, Silver Spring, MD 20993, 240–302–2942; or Abhilasha Nair, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2362, Silver Spring, MD 20993, 301–796–8317; or James Myers, 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, IRBs, and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. However, eligibility criteria are sometimes more restrictive than necessary, and expanding eligibility criteria to be more inclusive is one trial design consideration that may improve the diversity of clinical trial populations. This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this draft guidance includes recommendations to consider appropriate use of laboratory values as trial eligibility criteria and intends to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug.

Appropriately broadening cancer trial eligibility criteria can improve the generalizability of trial results and provide a more detailed characterization of the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants

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

ACTION: Request for public comment.

SUMMARY: HRSA's Federal Office of Rural Health Policy (FORHP) utilizes clear, consistent, and data-driven methods of defining rural areas in the United States for the purposes of determining eligibility for its rural health grant programs. FORHP monitors ongoing national research and, as appropriate, considers updates to its definition. Because access to needed health care is likely to be reduced when roads are most difficult to traverse, with this notice, FORHP proposes to modify the definition of rural areas by integrating the new Road Ruggedness Scale (RRS) released in 2023 by the Economic Research Service (ERS) of the U.S. Department of Agriculture, which characterizes topographic variability, or ruggedness, of roads. This proposal does not impact rural areas included in the current FORHP definition. This notice seeks public comment on FORHP's proposal. This notice also includes a technical clarification explaining how FORHP will use Census data to identify outlying Metropolitan Statistical Area counties that qualify as rural in future updates given the U.S. Census Bureau's 2020 Census terminology changes that removed the categories of Urban Clusters and Urbanized Areas.

DATES: Submit comments no later than May 28, 2024.

ADDRESSES: Comments should be submitted to *ruralpolicy@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Greta Stuhlsatz, Statistician, Policy Research Division, FORHP, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443–0835; and *ruralpolicy@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 711 of the Social Security Act (42 U.S.C. 912) directs FORHP to advise the Secretary of HHS on policies affecting rural hospitals and health care and coordinating activities within HHS that relate to rural health care. Since the 1990s, FORHP has administered grants that support activities related to increasing access to health care in rural areas. FORHP's authorizing statute does not, however, include a definition of ''rural area.'' To carry out this charge, FORHP monitors ongoing national research and analysis efforts related to defining geographic areas and rurality. As new methods and data become available, FORHP may consider revisions to the definition.

Historically, there have been two principal definitions of ''rural'' that were in use by the Federal Government: The U.S. Census Bureau urban-rural classification (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) and the Office of Management and Budget's definition of metropolitan, also called metro, areas (*https://www.census.gov/programs-surveys/metro-micro.html*). Neither definition defined ''rural'' directly, but rather defined areas as either ''urban,'' with all other territory being ''rural,'' or as ''metro,'' with all other territory being ''non-metro.''

Current FORHP Definition of Rural Area

FORHP currently designates the following areas as rural for purposes of FORHP's grant programs: [1]

(1) All non-metro counties,

(2) All outlying metro counties without an Urbanized Area,

(3) All metro census tracts with Rural Urban Commuting Area (RUCA) codes 4–10, and

(4) Metro census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3.

FORHP's current definition finds that 19.7 percent of the population, or approximately 60.8 million people, live in rural areas, and classifies 86 percent of the land area of the United States as rural (based on 2010 Census data; all data will be updated when updated RUCA codes are available using data from the 2020 Census). Information on whether individual addresses are within a rural area can be identified in a search tool at the HRSA Data Warehouse.[2] HRSA updates the search tool as needed to assist rural health grant applicants.

Adding Rugged Terrain Data to the Definition of Rural Area

FORHP's definition of rural area was last updated in 2021.[3] At that time, some commenters suggested that FORHP should further modify the definition of rural area to account for difficult and mountainous terrain because travel on roads through such terrain is more difficult and time-consuming. FORHP did not have national data that could consistently identify areas of difficult terrain.

In 2023, the ERS published a report, *Characterizing Rugged Terrain in the United States,*[4] which describes the measurement of topographic variation using the Terrain Ruggedness Index. The ERS conducted a study to analyze how population, population density, and income vary by ruggedness and rurality. The ERS produced two scales:

(1) The Area Ruggedness Scale (ARS) measures the changes in elevation for all terrain and classifies census tracts as: (1) level, (2) nearly level, (3) slightly rugged, (4) moderately rugged, (5) highly rugged, and (6) extremely rugged. This characterizes overall ruggedness in the entire tract.

(2) The RRS measures the changes in elevation beneath roads and classifies census tracts as: (1) level, (2) nearly level, (3) slightly rugged, (4) moderately rugged, and (5) highly rugged. This characterizes overall ruggedness along roads in the tract.[5]

The RRS, or roads-only scale, helps to study the impact of rugged terrain on travel by vehicle. Based on the ERS analysis of the RRS, population density was highest, on average, for nearly level census tracts (5,514 people per square mile) and lowest for highly rugged census tracts (3,390 people per square mile).

TABLE 1—RRS CATEGORIES AND CENSUS TRACTS

RRS category	Number of census tracts	Percent of census tracts
1—Level	47,740	65.6
2—Nearly level	16,297	22.4
3—Slightly rugged	5,518	7.6
4—Moderately rugged	1,956	2.7
5—Highly rugged	1,254	1.7
Total	72,765	100.0

FORHP is proposing to expand its definition of rural by incorporating the RRS into the definition for purposes of FORHP's grant programs. All areas included in the current definition would remain included. The RRS focuses on roads and the difficulty of travelling in mountainous terrain, while the ARS more generally classifies the topography of the tract's terrain. Access to needed health care is likely to be reduced when the roads are most difficult to traverse. FORHP proposes including census tracts of at least 20 square miles in area in metro counties

[1] See the notice ''Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,'' 85 FR 59806 (Sept. 23, 2020), for a full description of the methods and data sources used to develop FORHP's definition of rural areas. See the notice ''Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,'' 86 FR 2418 (Jan. 12, 2021), for FORHP's current definition of rural areas. See Defining Rural Population, *https://www.hrsa.gov/rural-health/about-us/what-is-rural.*

[2] HRSA Data Warehouse: *https://data.hrsa.gov/tools/rural-health.*

[3] ''Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants.'' 86 FR 2418 (Jan. 12, 2021).

[4] Research Report No. ERR–322, August 2023. Available at *https://www.ers.usda.gov/publications/pub-details/?pubid=107027.*

[5] ARS and RRS data are available at *https://www.ers.usda.gov/data-products/area-and-road-ruggedness-scales/.*

with RRS 5 (highly rugged) and RUCA code 2 or 3 in our definition of rural area (tracts with RUCA codes 4–10 regardless of RRS are already included). Some small area tracts within or on the edge of cities can have rugged terrain (*e.g.,* State or local parks), but they are very small size and adjacent to major population centers.

FORHP estimates that including census tracts that are at least 20 square miles in area with RRS 5 and RUCA 2–3 in the definition of rural area would add 84 census tracts and approximately an additional 304,834 people to the 60,758,275 people currently living in FORHP-designated rural areas, an increase of 0.5 percent in the total number of people living in rural areas. The number of eligible census tracts by State is included in table 2.

Only tracts that meet all criteria—RRS 5 and RUCA 2–3 with an area over 20 square miles—would be newly eligible under this proposed update. Tracts with RRS 5 and RUCA code 1 could not be classified as rural areas as tracts with RUCA code 1 contain populations from urban areas with over 50,000 residents. Additionally, the RUCA code 1 tracts located in metro counties are part of the metropolitan area core and have primary commuting flow within the urban area.[6] For example, San Francisco, California has 31 census tracts with RRS 5 and RUCA code 1, and these small areas with rugged terrain inside the metropolitan area core are not rural in character.

TABLE 2—NUMBER OF CENSUS TRACTS WITH RRS 5 AND RUCA CODE 2 OR 3 AND AREA OVER 20 SQ. MILES, BY STATE

State	New tracts
CA	24
OR	16
NC	12
WA	9
TN	7
CO	6
WV	6
MT	2
AK	1
MD	1
Total	84

Note: Data in this table are based on 2010 census tract geographies. For a complete list of impacted census tracts see: *https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files.*

FORHP's proposal to modify our definition of rural area for purposes of FORHP's grant programs reflects efforts to be responsive to stakeholder feedback and target programs towards the intended communities. Other rural definitions for other purposes may be set by statute or regulation or be designed to meet different program goals.

Notification of FORHP's Technical Clarification in Response to the U.S. Census Bureau's 2020 Census Terminology Changes Removing Urban Clusters and Urbanized Areas

Prior to the 2020 Census, the U.S. Census Bureau designated two categories of urban areas—Urban Clusters (with a population of 2,500 to 49,999) and Urbanized Areas (with a population of 50,000 or more). With the elimination of these sub-categories to differentiate urban areas with large and small populations, the U.S. Census Bureau now only designates urban areas (population of 5,000 and up or housing units of 2,000 or more) and does not sub-categorize urban areas by size. FORHP's rural definition excludes outlying metro counties with an *Urbanized Area.* To retain the distinction between urban areas with population over and under 50,000 in FORHP's definition of rural area, FORHP will identify and categorize urban areas based on population size. With this technical clarification, the definition, ''all outlying metro counties with no urban population from an urban area of 50,000 or more people,'' will replace ''all outlying metro counties without an urbanized area.''

FORHP will use the urban area population counts published by the U.S. Census Bureau in the list of qualifying urban areas for the 2020 Census (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) to sub-categorize urban areas as less than 50,000 people (*e.g.,* a population of 49,999 or fewer) and as 50,000 or more people in the next update to rural area data files. Consistent with our current definition, FORHP will consider outlying metro counties without population from urban areas with 50,000 or more people as rural areas, and the entire county would be considered a rural area for our grant programs.

There are 327 outlying metro counties in the Office of Management and Budget's Bulletin No. 23–01, released July 21, 2023, that have no population part of an urban area with 50,000 or more people. Outlying metro counties with any population from urban areas with 50,000 or more people would not be considered rural areas, however census tracts within those counties would be considered rural areas if they meet the RUCA criteria or the RUCA and RRS criteria, as applicable.

Proposed FORHP Definition of Rural Area Incorporating the RRS and the Technical Clarification in Response to Census Terminology Changes

FORHP proposes to designate the following areas as rural for purposes of FORHP's grant programs:

(1) Non-metro counties,

(2) Outlying metro counties with no urban population from an urban area of 50,000 or more people,

(3) Census tracts in metro counties with RUCA codes 4–10,

(4) Census tracts in metro counties of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3, and

(5) Census tracts in metro counties with RRS 5 and RUCA codes 2–3 that are at least 20 square miles in area.

Request for Public Comment

FORHP is proposing to modify the current definition of rural area for purposes of FORHP's grant programs. FORHP seeks comments from the public on the proposed use of the RRS to identify rural areas as described above.

This request for comments is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This request does not commit the Government to contract for any supplies or services or make a grant or cooperative agreement award or take any other official action. Further, HRSA is not seeking proposals through this request for comments and will not accept unsolicited proposals.

Carole Johnson,

Administrator.

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BILLING CODE 4165–15–P

[6] See the description of Rural-Urban Commuting Area Codes at *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to