Background and Brief Description

Although the HIV diagnosis rate among Hispanic/Latino Americans (H/L) has decreased in the United States (from 17.6/100,000 in 2014 to 11.0/100,000 in 2019), H/L continue to be disproportionately affected by HIV. H/L account for 18.7% of the US population and in 2019 they accounted for 29% of new HIV diagnoses, the majority (85%) of which were among H/L gay, bisexual and other men who have sex with men (HLMSM). Medical mistrust (MM) is a social determinant of health associated with HIV disparities (*e.g.*, low PrEP willingness and adherence) among HLMSM that prevents and delays access and engagement in HIV prevention and care services (*e.g.*, PrEP, ART). To date, most MM studies in the United States have focused on Black/African American persons. The few studies that have examined MM among H/L are mostly in non-HIV fields (*e.g.*, reproductive health and chronic diseases, such as cancer screening). The literature highlights the need for research about MM among HLMSM.

Because its root causes in this priority group are unknown, the goals of this collection are to understand pathways that lead to MM in HLMSM, and to capture variations in MM drivers among different H/L subgroups (*e.g.*, Indigenous, Mexican, Puerto Rican, Salvadoran, Columbian). Methods used to collect data during this project include (1) In-depth interviews, focus groups, and quantitative surveys with HLMSM and (2) key informant interviews and focus groups with health care providers and H/L leaders/gatekeepers. Projects collecting information under this request should: (1) identify the root causes of MM and opportunities to implement interventions that can make HIV-related services trusted and acceptable for HLMSM to help increase HLMSM access to, and utilization of, HIV prevention and care services; (2) contribute toward achieving Ending the HIV Epidemic in the U.S. (EHE) goals; and (3) respond to the National HIV Strategic Plan health disparities goals.

CDC awarded a research cooperative agreement to three academic institutions (Johns Hopkins University [JHU]; the University of California, San Francisco [UCSF]; and Wake Forest University [WFU]) through a Notice of Funding Opportunity (NOFO) PS23–006. The total estimated annualized burden hours requested are 2,580. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
HLMSM	In-Depth Interview Screener (JHU)	66	1	10/60	11
HLMSM	In-Depth Interview Guide (JHU)	60	1	75/60	75
HLMSM	Eligibility Questionnaire (WFU)	70	1	5/60	6
HLMSM	Demographic Questionnaire (WFU)	60	1	15/60	15
HLMSM	In-Depth Interview Guide (WFU)	60	1	1.5	90
HLMSM	In-Depth Interview Screener (UCSF)	48	1	10/60	8
HLMSM	In-Depth Interview Guide (UCSF)	40	1	45/60	30
HLMSM	Focus Group Interview Screener (JHU).	55	1	10/60	9
HLMSM	Focus Group Interview Guide (JHU)	50	1	75/60	63
Key Informants (Service Providers and Community Leaders).	Focus Group Interview Screener (JHU).	55	1	10/60	9
Key Informants	Focus Group Interview Guide (JHU)	50	1	75/60	63
Key Informants	In-Depth Interview Screener (JHU)	55	1	10/60	9
Key Informants	In-Depth Interview Guide (JHU)	50	1	75/60	63
Key Informants	Demographic Questionnaire (WFU)	30	1	10/60	5
Key Informants	In-Depth Interview Guide (WFU)	30	1	1.5	45
Key Informants	In-Depth Interview Screener (UCSF)	12	1	10/60	2
Key informants	In-Depth Interview Guide (UCSF)	10	1	1	10
HLMSM	Cross-Sectional Survey Screener (JHU).	1,788	1	10/60	298
HLMSM	Cross-Sectional Survey (JHU)	1,625	1	1	1,625
HLMSM	Questionnaire Screener (UCSF)	144	1	10/60	24
HLMSM	Questionnaire (UCSF)	120	1	1	120
Total					2,580

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Tribal Child Support Enforcement Direct Funding Requests: (Office of Management and Budget #0970–0218)

AGENCY: Office of Child Support Services, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF) is requesting to extend approval of revisions to an approved information collection the Tribal Child Support Enforcement Direct Funding Requests (Office of Management and Budget (OMB) #0970–0218). These revisions

were approved under an emergency approval for 6-months and included a new requirement for Tribes or Tribal organizations to provide that charging fees and recovering costs will not be permitted.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004 at 69 FR 16638, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program, a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV–D program. If a Tribe or Tribal organization intends to make any substantial or material changes, a Tribal IV–D plan amendment must be submitted for approval. Tribes and Tribal organizations must have an approved plan and submit any required plan amendments in order to receive funding to operate a Tribal IV–D program. Through an emergency approval request, OCSS included a new requirement for Tribes and Tribal organizations to provide that charging fees and recovering costs will not be permitted. This is due to the Final Rule on the Elimination of the Non-Federal Share published on February 12, 2024 (see 89 FR 9784). Tribes and Tribal organizations that charge fees and recover cost must submit a plan amendment demonstrating compliance with the proposed new requirement, in accordance with 45 CFR 309.35(d). This is a one-time submission. Only three Tribal child support programs report data on the collection of fees and recovered costs. This request is to extend approval with no changes.

Respondents: Tribes and Tribal Organizations.

Burden Estimates

The following burden estimates include new burden associated with the change in requirement, as well as existing burden under OMB #: 0970–0218.

Instrument	Total number of respondents	Total number of responses per respondent (over three years)	Burden hours per response	Total burden hours (over three years)	Annual burden hours
45 CFR 309—New Plan	10	3	480	14,400	4,800
45 CFR 309—Plan Amendment	60	*2	105	18,900	6,300
45 CFR 309—Plan Amendment—Charging fees and recovering	3	1	3	9	3
Estimated Burden Hours and Costs				33,309	11,103

*This estimate is based on an average number of about 2 amendments submitted per year per Tribe, but that does vary annually and by Tribe.

Authority: Title IV–D of the Social Security Act; 45 CFR 309.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2217]

Determination of Regulatory Review Period for Purposes of Patent Extension; Rybrevant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Rybrevant and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 26, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. eastern time at the end of April 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way: