

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–1235 Docket No. CDC–2021–0076]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a continued information collection project titled “Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth.” This is a generic information collection package that supports qualitative and quantitative data collection from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

DATES: CDC must receive written comments on or before October 1, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0076 by any of the following methods:

- *Federal eRulemaking Portal:* *Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth (OMB Control No. 0920–1235, Exp. 05/31/2022)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the extension of a Generic information collection package (OMB Control No. #0920–1235, Exp. 05/31/2022) that supports collection of quantitative and qualitative information from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs, and their health risk factors and access to health care are addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require that foundation of scientific evidence. Assessment of programmatic practices for adolescents helps to assure effective and evidence-based sexual risk reduction practices and efficient use of resources. Such assessments also help to improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored for them.

The information collection requests under this generic package are intended to allow for data collection with two types of respondents:

- Adolescents (11–19 years old) of middle and high school age; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (*e.g.*, food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings;

and non-biological parents such as adoptive, foster, or stepparents.

The types of information collection activities included in this generic package are:

(1) Quantitative data collection through electronic, telephone, or paper questionnaires to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age.

(2) Qualitative data collection through electronic, telephone, or paper means to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and in-depth interviewing through group interviews, and cognitive interviewing.

For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes,

behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels.

For parents and caregivers, data collection instruments will include questions on demographic characteristics as well as parents'/ caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined, and will include a cross-walk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data

collection instruments will be pilot-tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included. Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children. All data collection procedures will receive review and approval by an Institutional Review Board for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB-approved protocols. These will be described in the individual information collection requests put forward under this Generic package.

The table below provides the estimated annualized response burden for up to 15 individual data collections per year under this generic clearance at 57,584 hours. Participation of respondents is voluntary. There is no cost to participants other than their time.

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 (in hours)
Middle and High School Age Adolescents.	Youth Questionnaire	20,000	1	50/60	16,667
Middle and High School Age Adolescents.	Pre/Post youth questionnaire	10,000	2	50/60	16,667
Middle and High School Age Adolescents.	Youth interview/focus group guide ...	3,000	2	90/60	9,000
Parents/caregivers of adolescents	Parent/Caregiver questionnaire	7,500	2	25/60	6,250
Parents/caregivers of adolescents	Parent/Caregiver interview/focus group guide.	3,000	2	90/60	9,000
Total					57,584

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0758]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 7, 2021, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this

advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0758. The docket will close on October 6, 2021. Submit either electronic or written comments on this public meeting by October 6, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 6, 2021. The <https://www.regulations.gov> electronic filing