**Generic Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**OMB#: 0920-1154**

**Title: Adolescent Mental Health Journey Mapping Project**

Supporting Statement A

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**Table of Contents**

[**JUSTIFICATION**](#_4i7ojhp) **[4](#_4i7ojhp)**

[1. Circumstances Making the Collection of Information Necessary](#_gjdgxs) [4](#_gjdgxs)

[2. Purpose and Use of Information Collection](#_30j0zll) [4](#_30j0zll)

[3. Use of Information Technology and Burden Reduction](#_1fob9te) [5](#_1fob9te)

[4. Efforts to Identify Duplication and Use of Similar Information](#_3znysh7) [5](#_3znysh7)

[5. Impact on Small Businesses or Other Small Entities](#_2et92p0) [5](#_2et92p0)

[6. Consequences of Collecting the Information Less Frequently](#_tyjcwt) [5](#_tyjcwt)

[7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5](#_3dy6vkm) [5](#_3dy6vkm)

[8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency](#_1t3h5sf) [5](#_1t3h5sf)

[9. Explanation of Any Payment or Gift to Respondents](#_4d34og8) [5](#_4d34og8)

[10. Protection of the Privacy and Confidentiality of Information Provided by Respondents](#_2s8eyo1) [6](#_2s8eyo1)

[11. Institutional Review Board (IRB) and Justification for Sensitive Questions](#_17dp8vu) [6](#_17dp8vu)

[12. Estimates of Annualized Burden Hours and Costs](#_3rdcrjn) [6](#_3rdcrjn)

[13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers](#_26in1rg) [7](#_26in1rg)

14. Annualized Cost to the Government [7](#_lnxbz9)

[15. Explanation for Program Changes or Adjustments](#_35nkun2) [7](#_35nkun2)

[16. Plans for Tabulation and Publication and Project Time Schedule](#_1ksv4uv) [7](#_1ksv4uv)

[17. Reason(s) Display of OMB Expiration is Inappropriate](#_2jxsxqh) [8](#_2jxsxqh)

[18. Exceptions to Certification for Paperwork Reduction Act Submissions](#_z337ya) 8 [8](#_1y810tw)

**List of Attachments**

Attachment 1: Email

Attachment 2: Screening Surveys

Attachment 2a: LGBTQ+ Teen Screening Survey

Attachment 3: Consent & Assent Form

Attachment 4: Adolescent Interview Discussion Guide

Attachment 5: Adolescent Focus Group Discussion Guide

Attachment 6: Adolescent Brainstorming Session Discussion Guide

Attachment 7: Privacy Applicability Form

Attachment 8: IRB Approval letter

Attachment 9: Screening Surveys Spanish

**Summary**

|  |
| --- |
| **Goal of the study**: This project is intended to map the experiences of girls and nonbinary adolescents (ages 13-17) seeking and accessing mental health care in rural America, with a focus on identifying trusted resources and building resiliency for teens through social support systems, coping skills, and mental health literacy.  **Intended use of the resulting data**: The information collected for this qualitative formative testing will be used to inform CDC’s journey map(s) and inventory of recommended prevention strategies. The data collected through this work and outputs of this project will be for CDC internal use only and is not intended for external publication.  **Methods to be used to collect:** Data will be collected through a combination of virtual and in-person discussions.  **The subpopulation to be studied:** The population of focus for the semi-structured interviews, focus groups, and brainstorming sessions is girls and nonbinary adolescents (ages 13-17) in rural areas of Montana, New Mexico, and North Carolina. We are looking to recruit a diverse sample of adolescent girls and those identifying as nonbinary, including all sexual orientations, and diverse racial and ethnic groups.  **How data will be analyzed**: We will analyze and identify major themes by conducting thematic analysis, a combination of notes, as well as the transcripts will be analyzed. The research team will analyze themes from across the data sources as well and across subgroups and respondent groups to compare and contrast findings. |

# JUSTIFICATION

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC), Office of Policy and Partnerships (OPP) requests OMB approval of a new generic information collection (GenIC) under the generic information collection entitled *Generic Clearance for CDC/ATSDR Formative Research and Tool Development* for a period of 10 months as the conclusion date of this project is late September 2024.

According to the US Centers for Disease Control and Prevention (CDC)’s 2021 Youth Risk Behavior Survey, 29% of high school students experienced poor mental health during the past 30 days, and female students were more likely than male students to experience mental health challenges. Additionally, those living in rural areas experience disparities in mental health outcomes compared to those living in metropolitan and suburban areas. As a response to this data and the national emergency for children and adolescent mental health declared in 2022, CDC’s National Center for Injury Prevention and Control’s (NCIPC) Office of Policy and Partnerships (OPP) is looking to better understand the mental health experiences of adolescent youth (ages 13-17) identifying as girls/female or nonbinary living in rural areas. We will not explicitly be asking youth about any traumatic experiences. This project is formative in nature and intended to guide CDC’s programmatic planning to address adolescent mental health needs in the US.

## 2. Purpose and Use of Information Collection

## The information collected for this qualitative formative testing will be used to inform CDC’s journey map(s) and inventory of recommended prevention strategies. The final report and journey map(s) are the only project deliverables, and other data files will be destroyed at the conclusion of the study in September 2024. The final report and journey map(s) will be used to inform and support the future of CDC’s work in adolescent mental health. The data collected through this work and outputs of this project will be for CDC internal use only and is not intended for external publication. We will not be sharing any identifiable data with partners. However, we intend to share synthesized, summarized findings from across all qualitative data collection to share learning with project partners.

The primary goals of this low-burden and low-cost project are to:

1. Better understand the experiences of girls and nonbinary adolescents (ages 13-17) seeking and accessing mental health care in rural America
2. Inform opportunities for this population for public health interventions and upstream prevention at CDC

To meet our project goals, we are guided by a set of overarching project questions we seek to answer across study participants. These questions include:

* How can we build resilience and foster positive mental health outcomes for adolescent girls and nonbinary youth by identifying key protective and risk factors?
* How could we bring awareness to the trusted resources that adolescent girls and nonbinary youth turn to when experiencing mental health challenges?
* How might we amplify cultural or community related strengths that bolster protective factors for adolescent girl and nonbinary youth mental health?
* How can we improve identification of mental health challenges and expedite the path to support for adolescent girls and nonbinary youth in rural areas?
* Are there non-traditional ways for adolescent girls and nonbinary youth in rural areas to access mental health support?
* Can we better understand the meaning of “mental health” to adolescent girls and nonbinary youth and the ways they invest in their own mental health?

To answer these questions, we will conduct primary data collection using in-person and virtual interviews, focus groups, and brainstorming sessions with girls and nonbinary adolescents (ages 13-17). A maximum of 30 adolescent interviews, 14 adolescent focus groups, and 8 adolescent brainstorming sessions will be conducted via an interactive in-person or virtual session between the participant(s) and the facilitator(s) using a communication interface consistent with Zoom Video Communications Inc. (Zoom) or at a community-based organization facility.

The semi-structured discussions with participants will follow the discussion guides. The discussion guides include questions/topics that will elicit feedback from the participants about their experiences with mental health, with a focus on social support systems, coping skills, and mental health literacy.

Interviews will be 60 minutes while focus groups and brainstorming sessions will be 90 minutes. Tables 1, 2, and 3 detail the general structure and the estimated time allocation by stage of the adolescent interviews, adolescent focus groups, and adolescent brainstorming sessions, respectively.

***Table 1: General Structure of Adolescent Semi-Structured Interview Sessions (60-minute discussion)***

|  |  |  |
| --- | --- | --- |
| Estimated Time | Stage | Description |
| ~2 minutes | Introduction | Facilitator(s) will introduce topic and obtain verbal consent for the session to be audio recorded. |
| ~3 minutes | Rapport building | Short introductions to create cohesion and build rapport with the interview participant (no last names) and an ice breaker question/activity if appropriate. |
| ~54 minutes | In-depth conversation | Facilitator(s) will initiate the major discussion topics and rely on the interview guide to ensure all topics are addressed. |
| ~1-2 minutes | Closure | The facilitator(s) will thank the interviewee for attending, answer any last questions, and let them know that the gift-card will be emailed to them within 1-2 weeks of the session. |

***Table 2: Structure of Adolescent Focus Group Sessions (90-minute discussion)***

|  |  |  |
| --- | --- | --- |
| Estimated Time | Stage | Description |
| ~3 minutes | Introduction | Facilitators will introduce topic and obtain verbal consent for the session to be audio recorded. |
| ~5 minutes | Rapport building | Short introductions to create group cohesion (no last names) and an ice breaker question/activity if appropriate. |
| ~80 minutes | In-depth investigation | Facilitator will initiate the major discussion topics and rely on the discussion guide to ensure all topics are addressed. |
| ~1-2 minutes | Closure | The facilitator will thank participants for attending, answer any last questions, and let them know that the gift-card will be emailed to them within 1-2 weeks of the session. |

***Table 3: Structure of Adolescent Brainstorming Sessions (90-minute discussion)***

|  |  |  |
| --- | --- | --- |
| Estimated Time | Stage | Description |
| ~3 minutes | Introduction | Facilitator(s) will introduce session and obtain verbal consent for the session to be audio recorded. |
| ~5 minutes | Rapport building | Short introductions to create group cohesion (no last names) and an ice breaker question/activity if appropriate. |
| ~80 minutes | Collaborative Feedback Discussions and Idea Generation | Facilitator(s) will initiate the major discussion topics and rely on the discussion guide to ensure all topics are addressed amongst the group. |
| ~2 minutes | Closure | Facilitator(s) will thank participants for attending, answer any last questions, and let them know that the gift-card will be emailed to them within 1-2 weeks of the session. |

## 3. Use of Information Technology and Burden Reduction

The screening surveys for the session will be conducted online via an online survey platform to limit burden on both the participants and the project team. Individuals will be selected via a convenience sampling approach, through meeting potential participants where they are with advertisements in community-based organization facilities and newsletters. The survey platform has built-in analytics, which will allow the research team to quickly analyze data. The team will use a visual guide/worksheet on the screen for participants to follow along and annotate during the virtual sessions. In person, the team will use printed copies of the visual guide available for participants to use for notetaking, drawing, and interactive engagement purposes. This is intended to provide an alternative avenue to encourage engagement throughout the session audience.

## 4. Efforts to Identify Duplication and Use of Similar Information

A literature review found no instances of similar information to be available. This information collection request represents a new effort – the first of its kind – to collect qualitative data from girls and nonbinary adolescents (ages 13-17) in an intend to map their experiences seeking and accessing mental health care in rural America. This study represents the first attempt to systematically assess this topic. There is no known information available that can substitute data collection.

## 5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. Some data collection involves from non-profit, community-based organizations, including YMCA of Southeastern North Carolina, YMCA Mountain States Alliance, Family YMCA of Los Alamos, North Carolina Native American Youth Organization, and Time Out Youth; however, these data collections will not have a significant impact on these non-profit organizations. The project team will be partnering with these local non-profit, community-based organizations that serve adolescent girls and nonbinary youth in rural communities to support a convenience sampling approach to recruitment.

## 6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection.

## 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

## 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice has already been published for the Generic Clearance. No Federal Register Notice is required for this GenIC submission.

B. A federal technology consultancy is the contractor for the data collection.

## 9. Explanation of Any Payment or Gift to Respondents

Krueger and Casey (2009) note that the gift helps emphasize to participants that the assessment is important, which in turn is intended to make them more inclined to make time to participate.[[1]](#footnote-3) To encourage and improve response rates for this project, each session participant will be given $50 per session in the form of a Visa gift card for their time within 1-2 weeks of the session. This can help minimize bias in the perspectives, improve the validity and reliability of the data, and ensure equitable treatment of project participants, all of which are of utmost importance in this project.

## 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCIPC’s Information Systems Security Officer, who has determined that the Privacy Act does not apply (**Attachment 7**). PII will only be used to screen for, and to contact, respondents who match the specified respondent profile for the session. PII will be collected via a web-based survey application as part of the prescreening process. PII for each selected individual will be destroyed before the conclusion of this effort in September 2024. Individuals not selected for a session will not be contacted and their information will immediately be deleted. PII will not be retained or used to link respondents’ individual comments during the session or during the analysis. All findings will be reported in the aggregate. PII will also not be used to describe the respondents in the room or to provide context to the analysis. Data are treated in a private manner, unless otherwise compelled by law. No paper documents with PII will be collected. Data containing PII will be disposed of as soon as session participants have been contacted and scheduled for sessions. Emails will be disposed of after the incentive has been sent to the participants. Participants will have the option to turn their Zoom camera on, but it will not be mandatory during any of the virtual sessions and only audio will be recorded for all sessions. Names of participants entering the Zoom group discussion will be changed to their first names only (last names will be removed) to protect the privacy of the individual.

Audio recordings and transcriptions will be stored on a secure, password-protected cloud storage. Audio will be recorded via Zoom and recordings will be encrypted and transcribed using Zoom’s transcription mechanism which will only be used by the project team to validate the transcribed audio. Transcripts of the audio recordings will be de-identified prior and during analysis. Access to audio and de-identified transcript files is limited to authorized project team personnel only. Session audio files will be destroyed once the session has been transcribed including deleting files from the password-protected cloud and any local file storage. All staff and contractors working on the project agree to safeguard the data and not to make unauthorized disclosures. Responses in published reports are presented in aggregate form and no individuals are identified by name.

All consent forms include appropriate information about privacy, including purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating.

Data will be kept private to the extent allowed by law.

## 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

*IRB Approval*

CDC has received IRB approval (**Attachment 8**) through Solutions IRB (FWA00021831).

*Sensitive Questions*

This data collection asks sensitive questions around teen mental health and asks individuals to provide their race, ethnicity, sexual orientation, and gender identity. This information is being collected to inform the journey map with the nuances of individuals’ lived experiences and track any significant differences or similarities in access to mental health care or potential prevention strategies. Additionally, race, ethnicity, sexual orientation, and gender identity data will be used to ensure there is a representative sample across race, ethnicity, age groups, and sexual orientation among the youth engaged in interviews, focus groups, or brainstorming sessions.

Parents and/or guardians of potential participants will receive a recruitment email explaining the purpose of the study invitation (**Attachment 1**) and be directed to the weblink if they are interested in their teen participating. Upon opening the weblink, the parent or guardian will complete an online screening survey to confirm eligibility and collect socio-demographic information of the adolescent (**Attachment 2**).

After completing the survey, the parent or guardian will be requested to fill out their contact information along with their adolescent’s name and email address and provide consent. The parental screening survey and consent form is available in Spanish (**Attachment 9)**. If the adolescent is interested in participating, the adolescent will fill out the screening survey via a secure survey link. The project team will confirm participation on a rolling basis and will attempt to ensure diversity across the full sample. As such, not all eligible youth will be invited to an interview, focus group, or brainstorming session depending on the distribution of demographic characteristics enrolled.

Once the list of potential participants is compiled with the completed guardian consent form, the project team will confirm date and time of the sessions. For virtual sessions, the communication will share instructions on how to rename themselves prior to joining the conversation. Parents/guardians will provide their consent and youth will provide assent according to the processes outlined above, except for youth recruited from LGBTQ+-focused organizations. We are requesting a waiver of parental consent for recruiting youth from LGBTQ+ focused organizations to participate in interviews, focus groups, and brainstorming sessions (**Attachment 2a**). We recognize that requiring parental consent may inadvertently disclose the sexual orientation or gender identity of a teen invited to participate in this study and thus introduces additional risks to LGBTQ+ youth who have not disclosed their identities to their parents/guardians. Seeking parental consent may result in harm of the teen by unsupportive parents/guardians and infringes on their rights to privacy. It has been established in other studies that the potential for family crisis that may ensue from youth sexual orientation and/or gender identity disclosures is a real risk and that seeking parental consent for studies recruiting LGBTQ+ youth may result in harm to the youth including rejection, relationship distancing, and abuse; these potential harms justify the request to waive parental consent requirements.[[2]](#footnote-4) Similar research with LGBTQ+ youth have used similar procedures to protect LGBTQ+ identifying youth.5 Teens and LGBTQ+ youth will be required to complete a Consent/Assent Form to participate in interviews, focus groups, and brainstorming sessions (**Attachment 3**).

## 12. Estimates of Annualized Burden Hours and Costs

Recruitment for the interviews, focus groups, and brainstorming sessions will be conducted via convenience sampling through partnerships with local community-based organizations. Interviews will take 60 minutes to complete while focus groups and brainstorming sessions will take 90 minutes to complete.

There is no cost to participants beyond the participation burden time. The table below provides the burden estimates for this study.

***Table 1. Estimated Annualized Burden Hours***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category of Respondent** | **Form Name** | **No. of Respondents** | **Participation Time (Hours)** | **Burden (Hours)** |
| Adolescent Participants (ages 13-17) and Parents of Interested Adolescent Participants | Email  (**Attachment 1**) | 343 | 15/60 | 86 |
| Screening Survey (**Attachment 2**) | 171 | 10/60 | 29 |
| LGBTQ Screening Survey **Attachment 2a**) | 172 | 10/60 | 29 |
| Teen Consent/Assent Form  (**Attachment 3**) | 206 | 10/60 | 35 |
| Adolescent Interview Discussion Guides (**Attachment 4**) | 30 | 1 | 30 |
| Adolescent Focus Group Discussion Guide (**Attachment 5**) | 112 | 1.5 | 168 |
| Adolescent Brainstorming Session Discussion Guide (**Attachment 6**) | 64 | 1.5 | 96 |
| **Totals** |  |  |  | **473** |

**\*Note:** Some adolescents may take part in multiple session types.

***12b****.* While the project team does not anticipate all adolescent participants make hourly wages, estimates of the annualized cost to adolescents for the burden hours for the sessions is derived from the federal minimum wage for covered nonexempt employees is $7.25 per hour, per the [Department of Labor website](https://www.dol.gov/general/topic/wages/minimumwage). The estimates of the annualized cost to adult for the burden hours for the collection of information is derived from the November 2023 average hourly wage of $34.23 across all occupations, per the [US Bureau of Labor Statistics website](https://www.bls.gov/news.release/empsit.t19.htm).

***Table 2. Estimated Annualized Burden Costs***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondents** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
| Adolescent Participants (ages 13-17) and Parents of Interested Adolescent Participants | Emails  (**Attachment 1**) | 86 | $34.23 | $ 2,943.8 |
| Screening Survey (**Attachment 2**) | 29 | $34.23 | $ 992.7 |
| LGBTQ Screening Survey (**Attachment 2a**) | 29 | $34.23 | $ 992.7 |
| Teen Consent/Assent Form  (**Attachment 3**) | 35 | $7.25 | $254 |
| Adolescent Interview Discussion Guides (**Attachment 4**) | 30 | $7.25 | $217.5 |
| Adolescent Focus Group Discussion Guide (**Attachment 5**) | 168 | $7.25 | $1,218 |
| Adolescent Brainstorming Session Discussion Guide (**Attachment 6**) | 96 | $7.25 | $696 |
| Total $7,314.6 | | | | |

## 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

This data collection does not involve other annual cost burdens to respondents or record keepers.

## 14. Annualized Cost to the Government

***Table 3. Annualized Costs to the Government***

|  |  |
| --- | --- |
| **Description of Services** | **Estimated Annualized Cost** |
| Contractor costs for labor, adolescent data collection, and other overhead costs, per 3 months of the contract year + hard costs (travel, participant compensation, and independent IRB review) | **$162,290** |

## 15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

## 16. Plans for Tabulation and Publication and Project Time Schedule

All activities for the project are expected to be completed within 10 months after IRB approval.

## 17. Reason(s) Display of OMB Expiration is Inappropriate

None; the display of the OMB expiration date is not inappropriate.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

None; there are no exceptions to the certification.

**References**

Krueger, R. A., & Casey, M. A. (2009). Focus groups: A practical guide for applied research (4th ed.). San Francisco: Sage

1. Krueger, R. A., & Casey, M. A. (2009). Focus groups: A practical guide for applied research (4th ed.). San Francisco: Sage [↑](#footnote-ref-3)
2. Schelbe, L., Chanmugam, A., Moses, T., Saltzburg, S., Williams, L. R., & Letendre, J. (2014). Youth participation in qualitative research: Challenges and possibilities. *Qualitative Social Work*, *14*(4), 504–521. https://doi.org/10.1177/1473325014556792 [↑](#footnote-ref-4)