

Request for Sub-collection under the Generic ICR:
Formative Research and Tool Development
OMB 0920-0840, Expiration Date 01/31/2019

Formative Research on Resilience and Transgender Youth

Supporting Statement A

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Supported by:

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Goal: The goal of this study is to conduct formative research to assess protective factors available to transgender youth which may enable improved health and welling and enable avoidance of HIV/STD. The CDC’s Division of Adolescent and School Health’s (DASH) strategic plan has outlined the prevention needs of gender minority, or transgender, youth as a division priority. This data collection will provide data and reports for CDC DASH that describe the protective factors that are relevant and available to transgender youth.

Intended use of resulting data: This data collection will be used to direct CDC DASH research and programmatic efforts that involve transgender youth, in order that the specific protective factors that are most relevant to HIV/STD prevention among this population can be strategically incorporated into DASH activities. These findings may also be of use to local community based organizations that serve transgender youth.

Methods: This data collection uses qualitative, in-depth interviews. Interviews will be conducted with up to 48 transgender youth. Interviews are designed to take between 60-90 minutes and cover the topics of gender identity, relationships with family and friends, and experiences in the medical system and school.

Subpopulation to be studied: In-depth interviews will be conducted with up to 48 transgender youth from ages 15-24 who live or use social services in the Atlanta Metro area.

Data analysis: Analysis of data from interviews will be done through thematic analysis and involve the steps of iterative code development, establishment of intercoder reliability, use of qualitative data analysis software (such as NVivo10), and identification of major themes within the data.

Section A: Justification for the Information Collection

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health (DASH), requests OMB approval for a new information collection entitled “Formative Research on Resilience and Transgender Youth” under the Formative Research and Tool Development Generic Clearance (OMB #0920-0840, expires 01/31/2019). The project proposes to conduct formative research to assess protective factors available to transgender youth which may enable improved health and welling and enable avoidance of HIV/STDs. The prevention needs of gender minority, including transgender, youth have been identified by CDC DASH as a division priority. This data collection will provide data and reports for CDC DASH that describe the protective factors that are relevant and available to transgender youth. These reports will inform future quantitative surveys about transgender youth and HIV/STD prevention and contribute to the development of behavioral health interventions for transgender youth.

Transgender youth are vulnerable to health conditions like suicide, substance use, and HIV (Herbst et al., 2008; Reisner, White, Bradford, & Mimiaga, 2014; Reisner, Greytak, Parsons, & Ybarra, 2015). The term ‘transgender’ refers to people whose assigned sex at birth differs from their gender identity or gender expression (Fenway, 2010). Transgender people encounter high degrees of stigmatization as a result of this “discordance” between their birth sex and lived gender, as evident in the high rates of harassment, violence, discrimination, and childhood abuse among transgender populations (Grossman & D’Augelli, 2006; Reisner et al., 2014). Transgender youth are particularly vulnerable to these adverse outcomes, given that the traditional sites of support for positive youth development like family and schools often are places where transgender youth encounter frequent discrimination (Factor & Rothblum, 2007; Grossman & D’Augelli, 2006; Reisner et al., 2015). Such continuous discrimination takes a sustained toll on health (Meyer, 2003; Reisner et al., 2015) and transgender people are more likely to report suicidal ideation and attempt than individuals who are not transgender (Reisner et al., 2014). Transgender youth report higher rates of substance use than non-transgender youth (Reisner et al., 2015). Among transwomen (male-to-female transgender people), rates of HIV infection are well above the general population (Herbst et al., 2008). Given this constellation of risk factors and negative health outcomes, this data collection seeks to identify and describe protective factors which can improve well-being among transgender youth. Factors that are considered to be protective can then be incorporated into future structured research or program evaluation efforts.

Resilience refers to the process of positive functioning in the face of risk or deficit (Fergus & Zimmerman, 2005; Richardson, 2002). An individual’s ability to be resilient is largely facilitated by the presence or absence of protective factors. Protective factors are characteristics, conditions, and behaviors that reduce the effects of stressful life events, increase an individual’s ability to avoid risks or hazards, and promote social and emotional competence (Kipke, 1999). Protective factors exist across multiple social-ecological levels. Protective factors that occur within the individual are commonly referred to as internal *assets* (e.g., self-esteem, coping skills, hope, confidence), while protective factors that exist at higher levels of the social ecology (i.e., relationship, community, societal levels) are commonly referred to as external *resources* (e.g., mentors, parents, safe neighborhoods, community organizations; Fergus & Zimmerman, 2005). While protective factors uniformly diminish the influence of risk in individuals’ lives, external resources exist further away from the individual within the social ecology, and thus create the conditions in which internal assets develop (Fergus & Zimmerman, 2005). For example, a youth who lives in a safe neighborhood and has the support of his or her parents may in turn develop more coping skills and confidence. Both protective assets and resources assets are of interest to health science, as they can be leveraged to eradicate or lessen the effects of health risks and improve an individual’s wellbeing (Fergus & Zimmerman, 2005; Kirby & LePore, 2007; Resnick et al., 1997). As such, identifying protective factors relevant to transgender youth is critical to combatting the disproportionate burden of HIV/STDs affecting this population.

A recent systematic literature review conducted by CDC/DASH staff revealed that current research on protective factors for transgender youth is limited; it remains unclear which protective factors best reduce the risk of HIV and STDs among transgender youth (Beltran et al., in progress). In order for CDC/DASH to develop culturally relevant quantitative research, interventions, and health messaging for transgender youth, more information is needed about the protective factors that can impact this population. This study aims to understand which external

resources (e.g., supportive teachers) transgender youth credit as helping them to cultivate their internal assets (e.g., self-efficacy), which in turn may aid in their avoiding negative health outcomes like HIV and STDs. Through this formative data collection, we seek to meet the following 3 objectives: (1) Describe the protective factors (i.e., resources, assets) that transgender youth identify as important to keeping them healthy, happy, and strong; (2) Identify key actions from individuals (e.g., parents, school staff) and organizations (e.g., schools, community organizations) that transgender youth discuss as needed to increase their ability to be healthy, happy, and strong; and (3) Generate hypotheses about how these protective factors influence the health of transgender youth to inform future quantitative research (i.e., relationships between resources and assets).

CDC is authorized to collect the data described in this request by Section 301 of the Public Health Service Act (42 USC 241). A copy of this enabling legislation is provided in **Attachment 1**. In addition to this legislation, there are national initiatives and programs that this data collection would serve to support, including but not limited to:

- The *National Prevention Strategy* (NPS) calls for “medically accurate, developmentally appropriate, and evidence-based sexual health education.” The NPS encourages the involvement of parents in educating their children about sexual health, the provision of sexual and reproductive health services, and the reduction of intimate partner violence.
- *CDC Winnable Battles*, including prevention of HIV infection and teen pregnancy prevention (TPP), have been chosen by CDC based on the magnitude of the health problems and the ability to make significant progress in improving outcomes. These are public health priorities with large-scale impact on health with known, effective strategies to address them.

A.2 Purpose and Use of the Information Collection

The purpose of this data collection is to use qualitative interviewing methods to identify research methods and intervention content that may be appropriate for transgender youth, a population particularly vulnerable to HIV/STDs. Because the study of protective factors among transgender youth is relatively new within the health sciences, formative qualitative data are needed to describe and explore how protective factors operate in their lives, improve their health and wellbeing, and help them to avoid HIV/ STDs.

Each study participant will sit down with CDC/ ICF staff for a one-on-one in depth interview covering the topics of gender identity, relationships with family and friends, and experiences in the medical system and school. Because this interview was designed to better understand *protective factors* that enable youth to be healthy in the face of risk, the interview questions focus on positive aspects of youth’s lives. Interviews are estimated take between 60 and 90 minutes.

The proposed study design will answer the following questions:

1. How do transgender youth describe the role of protective factors at the individual, relationship, community, and societal levels in their lives and in relationship to their health?

2. What changes do transgender youth identify as needed in their relationships (e.g., with parents or health care providers) or within organizations (e.g., schools) to make them more health protective?

The information gathered through this study will provide crucial information for CDC DASH's research and programmatic efforts moving forward, and be disseminated through several channels. Research and programmatic recommendations will be disseminated internally through summative briefs and white papers, which may also be shared with community-based organizations in the Atlanta Metro Area serving transgender youth. Additional dissemination efforts may be sought to reach researchers and scholars conducting research on the health of transgender youth, and thus select findings may be shared through peer-reviewed publications in journals (e.g., *Journal of LGBT Health Research*, *Journal of Youth and Adolescence*) and at professional conferences (e.g., *American Public Health Association*, *Society for Adolescent Health and Medicine*).

Qualitative interviewing with a maximum of 48 volunteer participants who fit the eligibility criteria will be conducted. To participate, persons must identify as transgender (i.e., report their gender identity as different from the sex they were assigned at birth), be between the ages of 15-24, and reside or use services in the Atlanta Metro Area. The results of these qualitative interviews will be used by CDC DASH to develop research methods and health interventions appropriate for transgender youth.

Community based organizations (CBOs) sub-contracted by ICF International will assist with recruitment of target population. CBO recruiters, trained by ICF in research objectives, procedures, and roles and responsibilities with regard to recruitment and data integrity, will conduct outreach during regular CBO service delivery to this population, to share information about the study detailed in recruitment flyers and palmcards (**Attachment 5: Recruitment Flyer/ Palmcard Text**). Interested participants will complete a screener questionnaire (**Attachment 6: Eligibility Screener**) with CBO recruiters and schedule an interview to take place on location at the CBO with CDC investigators or ICF contractors. Interviewers will use a qualitative interview guide (**Attachment 3: Qualitative In-Depth Interview Guide**) to conduct an interview that will last between 60 and 90 minutes and be audio-recorded. Interviewers will make a record of interview experiences to assist in interpreting the interview transcripts (**Attachment 7: Interviewer Form**). Because the Interviewer Form is completed by study staff and not by respondents, it is acknowledged as a supplementary document for study implementation but is not included in the estimated burden to respondents.

The eligibility questionnaire (**Attachment 6: Eligibility Screener**) asks five questions to assess participant eligibility for the study, including month and year of birth, race/ ethnicity, gender identity, and the sex on their birth certificate, and contact information may be solicited in order to schedule face-to-face interviews; however, the eligibility questionnaire is administered and kept by staff sub-contracted CBOs and will not be kept by the CDC or accessed by CDC personnel. The gender identity and assigned sex at birth questions within the eligibility screener are modeled after the two-step method recommended by leading gender researchers as a reliable and valid method for assessing transgender identity (Williams Institute, 2013). All eligibility screeners will be kept in a secure location at CBOs and destroyed when the recruitment period has ended.

The qualitative interview guide (**Attachment 3: Qualitative In-Depth Interview Guide**) collects information on seven domains of interest:

- (1) Individual definitions of gender. There are 5 items with a total of 14 possible questions, including the sub-questions/ probes. Please note these questions are designed to establish rapport, allow for youth to define their own gender identity, and provide data for analytic considerations of how youth's self-defined gender may relate to conceptualizations of protective factors; these questions are not intended to inform development of measures of gender identity.
- (2) Individual definitions of health. There are 4 items, with a total of 13 possible questions, including sub-questions/ probes.
- (3) Individual level protective factors. There are 4 items, with a total of 7 possible questions, including sub-questions/ probes.
- (4) Interpersonal protective factors, including relationships with parents and romantic partners. There are 3 items, with a total of 24 possible questions, including sub-questions/ probes.
- (5) Community level protective factors, including schools, medical care, and local institutions/ events. There are 4 items, with a total of 62 possible questions including sub-questions/ probes.
- (6) Societal level protective factors. There is one item with a total of 5 possible questions, including sub-questions/ probes.

In addition, at the end of the interviews, interviewers will create a record of their experiences on the interviewer form (**Attachment 7**). This form asks the interviewer to reflect on the tone of the interview and note any unexpected events that might occur during the interview that could impact data quality. This form does not ask any additional questions of the participant. Interviewer forms will be kept as part of the data set and may be analyzed alongside interview data.

Audio-recordings of the interviews, their transcripts, and a copy of the completed interviewer form will be stored on the CDC server within a password protected and encrypted file storage folder created specifically for this project. Data collected within the qualitative interviews will not include any IIF.

A.3 Use of Improved Information Technology and Burden Reduction

Interviews will be conducted in-person by trained interviewers and audio-recorded with permission of the respondents. The use of audio-recordings may help reduce the amount of time required of participants because the interviewer will not have to pause for note-taking.

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

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has verified that there are no other collections that duplicate the study types included in this request.

A.5 Impact on Small Businesses or Other Small Entities

The collection request may impact local community-based organizations (CBOs) who will be hired by ICF International as sub-contractors to assist with recruitment efforts. Sub-contracted CBOs will be asked to identify appropriate staff members to conduct recruitment activities.

These CBO staff will be trained by ICF International and sign a Memorandum of Understanding (**Attachment 8: Memorandum of Understanding with CBOs**) which outlines their roles and responsibilities. Activities conducted by CBO partner organizations are funded through subcontracts and this information collection does not entail ongoing burden to CBO partner organizations. No other small business or other small entities will be involved in or impacted by this data collection.

A.6 Consequences of Collecting the Information Less Frequently

The study involves a one-time collection of data to begin Fall/Winter of 2016. Currently, the ICF International is contracted through a contract modification that will expire at the end of this fiscal year. In order to benefit from their expertise in recruiting this hard to reach population, this project must begin Fall/Winter 2016. If these data are not collected, CDC DASH will lack the information necessary to move forward strategic planning around the research and programmatic needs of transgender youth.

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

There are no special circumstances with this information collection package. This data collection request fully complies with the regulation 5 CFR 1320.5.

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

The 60-Day federal register notice was published for this collection on Thursday, June 25, 2015, Vol. 80, No. 122, pp. 36540 (**Attachment 2: Federal Register Notice**). No comments were received.

Internal and external experts consulted for this study are shown in **Table A.8**. All input from these sources was reviewed and addressed during the development of this data collection. There were no major problems that arose during the consultation, and all issues raised were resolved.

Exhibit A.8 Experts Consulted for Resilience and Transgender Youth Study

<p>Karen Kroeger, PhD Social and Behavioral Research and Evaluation Branch Division of STD Prevention Centers for Disease Control and Prevention 1600 Clifton Road, MS E-44 Atlanta, GA 30333 404-639-4488 404-639-8622 Knk2@cdc.gov</p>	<p>Emily Pingel, MPH Department of Sociology Emory University 201 Dowman Drive Atlanta, Georgia 30322 734-276-7054 epingel@emory.edu</p>
<p>Catherine Lesesne, PhD ICF International 3 Corporate Square, Suite 370 Atlanta, GA 30329 404-321-3211</p>	<p>Candace Sibley, MSPH Collaborating Center for Questionnaire Design and Evaluation Research Division of Research and Methodology National Center for Health Statistics</p>

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A.9 Explanation of Any Payment or Gift to Respondents

Participants will receive a \$50 gift card as a token of appreciation for completing the study. A benefit of this token method is that it does not require the collection of IIF by CDC or ICF, as the gift card will be handed directly to participants at the completion of the interview and does not require a name or contact information for usage. The token amount was determined after reviewing best practice with research on adolescents and young adults, which recommends that to attract participants token amounts need to be sufficient to offset the burden of time and travel (Bagley, Reynolds, & Nelson, 2007; Rice & Broome, 2004), and is consistent with CDC guidance that in “the cases of 90-minute in-person focus groups, interviews [...] the Agency may provide stipends of up to \$75”.

Additionally, in his memorandum for the president’s management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, “Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition) ...”. Transgender youth fall within the parameters of a hard-to-find population. Recent population estimates of transgender *adults* suggest they make up only 0.3% of the overall population of the US (Gates, 2011), and the percentage of adolescents and young adults with this identity is likely smaller still given the developmental context. The small number of transgender youth make recruitment efforts more difficult. Furthermore, transgender youth may not have adequate access to transportation and/ or may have unpredictable schedules, and the 60-90 minute interview represents a large portion of participant’s free time, and will require a substantial commitment. Participation in the interviews will take scarce discretionary time from youth who may have to also make special arrangements for transportation to the interview location.

Because transgender youth are young, difficult-to-engage, and critical to the success of this project we believe a token of appreciation will increase the attractiveness of this study to the potential participants and better engage them in the data collection process. Given the considerations outlined above and the estimated burden of the in-person interviews, token of

appreciation gifts to the respondents in the form of \$50 gift cards are proposed. Participants will receive their token of appreciation after they complete the in-depth interview.

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

The NCHHSTP Associate Director of Science Office determined that the Privacy Act does apply to the information collection, which is covered under the Privacy Act System Notice 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC”, which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

Some IIF will be collected for the purposes of participant recruitment (**Attachment 6: Eligibility Screener**), including a phone number or email address for recruiters to contact with appointment reminders; however, this IIF will remain completely separate from the data collected during the interviews. Recruiters will receive instruction on how to keep recruitment paperwork private and secure, and will be instructed to destroy all recruitment paperwork when the target sample size has been reached, approximately 4 months after the start of the study period. CDC is not receiving any identifiable information.

For the in-person interviews, no sensitive information is being collected. Although participants will provide contact information as part of the recruitment and scheduling process, this information will be used only for those purposes only and not be kept as part of the dataset. All interview recordings, transcripts, and the interviewer form will be kept separately from the contact information of the participants. Reports and articles based on the data will focus on overarching themes rather than specific stories. Articles may include quotes from individual participants to illustrate key themes; however, quotes will never be attributed to individuals by name or other IIF. All team members will be asked to sign privacy agreements and trained on security requirements. During data collection in the field, interviewers will maintain data collection materials in their possession or in secured storage at all times. All documents associated with the study will be collected and stored in a password-protected electronic file on a secure network accessible only by the study team through restricted access settings. These data files will be kept indefinitely for data analysis and dissemination efforts, but do not contain any IIF.

We anticipate no adverse impact of the proposed data collection on respondents’ privacy because *no individually identifiable information will be collected* as part of the dataset for this information collection. Should participants voluntarily disclose their names or the names of friends and family during the interview, this information will be omitted from the transcripts and stripped from the dataset. Participants will be informed that participating in this information collection is voluntary, and that they have the right to decline to participate or terminate the interview at any time.

Participants over the age of 18 will be given a consent form (**Attachment 4a: Consent Form (Age 18+)**) at the beginning of the in-depth interviews that will be read to the participants by the interviewer. The form has been written at a 7th grade reading level in order that all our participants are able to read and comprehend the document (i.e., a Flesch-Kincaid reading level

score of 7.0). The consent form describes the purpose of the study, specifies specific procedures that will be conducted, describes protections for the respondent's privacy and security, and reminds participants that their participation is completely voluntary.

As stated within CDC guidelines on writing assent forms, most adolescents over the age of 12 are considered capable of comprehending the contents of a standard consent form (CDC, 2015), and thus a process identical to the consent process will be conducted with participants between ages 15-17 using an assent form that largely resembles the consent documents (**Attachment 4b: Assent Form (Age 15-17)**).

No sensitive or individually identifiable information will be collected by CDC investigators or ICF contractors during the in-depth interviews. All notes and/ or recordings will be labeled with a unique numeric ID assigned to each participant and never include participant names or other IIF. Forms or paperwork associated with participant data (i.e., consent forms, interviewer notes, audio recordings) will be marked with the unique ID number and stored in a locked file cabinet accessible only to study personnel. During data collection in the field, interviewers will maintain data collection materials in their possession or in a secured storage container at all times, until they can be moved to a locked file cabinet on premises at the CDC. All documents associated with the study will be collected and stored in a password-protected electronic file on a secure network accessible only to study personnel. Responses and data reports will focus on aggregate thematic trends and any illustrative quotes used within data dissemination will be labeled with a pseudonym, never participants names.

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

IRB Approval

This study has been reviewed and approved by the CDC and the ICF IRBs (**Attachment 10**) which granted a waiver of parental permission for youth ages 15-17.

Sensitive Questions

The study entails a few questions about gender identity which may be deemed sensitive. These questions are necessary to ask as they directly address the overarching research questions of the study, and will allow CDC DASH to better meet the needs of transgender youth in research and programmatic efforts. This study does *not* ask any specific questions about sexual behaviors.

There is a minimal risk that some questions may make respondent feel uncomfortable. The consent includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the study at any time. We have compiled a list of transgender social services and resources in the Atlanta Metro area (**Attachment 9: Atlanta Metro Resources**) should participants need additional care after the interview process.

A.12 Estimates of Annualized Burden Hours and Costs

Information will be collected from 48 respondents (20 teen respondents; ages 15-19 and 28 young adult respondents; ages 20-24) using a Qualitative Interview Guide (**Attachment 6**). The estimated burden per response is based on pilot testing of the complete interview guide with four members of CDC's Sexual and Gender Minority Working Group. In the pilot tests, the average

time to complete the interviews including time for reviewing consent documents, answering participant questions, gathering needed information, and completing the instrument ranged from 60 to 90 minutes. Based on these results, we round to the top of the time range and estimate the time to complete as 1.5 hours per response for actual respondents. The total burden for all interviews is 72 hours. The same Qualitative Interview Guide will be used for all interviews.

In addition, all 48 respondents will participate in a brief Eligibility Screening interview (see **Attachment 3**). The estimated burden per response is 1 minute for a total of .50 burden hours.

The study design is based on recruitment targets, which factor in the respondent’s age group, sex on birth certificate, and race/ethnicity. The same screening and interview instruments are used for all information collection. There are minor differences in the consent/assent form depending on whether the respondent is 18-24 years of age (**Attachment 4a**) or 15-17 years of age (**Attachment 4b**).

Exhibit A.12.1 Estimated Annualized Burden to Respondents

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Teens, Age 15-19	Eligibility Screener (Att 6)	20	1	1/60	.5
Teens, Age 15-19	Qualitative Interview Guide (Att. 3)	20	1	1.5	30
Young Adults, Age 20-24	Eligibility Screener (Att 6)	28	1	1/60	.5
Young Adults, Age 20-24	Qualitative Interview Guide (Att. 3)	28	1	1.5	42
Total					73

The total estimated annualized burden is 73 hours.

A.12.B Estimated Annualized Costs

The annualized cost to respondents for burden hours is estimated at \$747.21. Based on recent data from the National Center for Education Statistics (http://nces.ed.gov/pubs2012/2012026/tables/table_30.asp), the median annual earnings for a full time worker between the ages of 15-19 years in the U.S. is \$17,600. From the annual wage of

\$17,600, and hourly rate of \$8.46 was calculated. We estimate that 20 of our respondents will be between the ages of 15-19, thus the resulting estimated annualized cost from this portion of our sample is \$4.23 from the eligibility screener and \$253.80 from the qualitative interview guide. The median annual earnings for a full time worker between the ages of 20-24 years in the U.S. is \$23,950. From the annual wage of \$23,950, an hourly rate of \$11.51 was calculated. We estimate that 28 of our participants will be between the ages of 20-24, thus the resulting estimated annualized cost for this portion of our sample is \$5.76 from the eligibility screener and \$483.42 from the qualitative interview guide.

Exhibit A.12.2 Annualized Cost to Respondents

Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Teens, Age 15-19 (20 respondents at 1 minute per screener)	Eligibility Screener	.5	\$8.46	\$4.23
Teens, Age 15-19 (20)	Qualitative Interview Guide	30	\$8.46	\$253.80
Young Adults, Age 20-24 (28 respondents 1 minute)	Eligibility Screener	.50	\$11.51	\$5.76
Young Adults, Age 20-24 (28)	Qualitative Interview Guide	42	\$11.51	\$483.42
Total				\$747.21

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no direct costs to the respondents or record keepers other than their time to participate in each information collection.

A.14 Annualized Cost to the Federal Government

Cost will be incurred to the government in personnel time for overseeing the project and data collection. CDC time and effort for overseeing the project, oversight of the contractor, and participation in data collection/ analysis is estimated at 10% for one GS-13 (step 4) level Atlanta-based employee for the year of the project. The average annual cost to the federal government for oversight, project management, and data collection/ analysis is \$9,714 (**Table A.14.1**).

CDC Foundation’s time and effort for data collection, processing, and analysis work is estimated at 25% of one Research Fellow for one year. This project is funded under Task Order# 200-2014-F-59670. The contractor, ICF International’s, costs are based on estimates provided by the contractor who consulted on research protocol development. With the expected period of performance, the annual cost to the federal government from the contractor is estimated to be approximately \$30,000. This includes the estimated cost of coordination with DASH, and working with sub-contracted CBOs on recruitment, data collection, and processing.

Exhibit A.14 Annualized and Total Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
<i>Direct Cost to the Federal Government</i>		
CDC oversight of contractor and project, participation in data collection and analysis	1 CDC Health Scientist at 10% time (GS-13)	\$9,714
Subtotal, Direct Costs to the Government per Year		\$9,714
<i>Staff, Contractor, and Other Expenses</i>		
CDC Foundation assistance with data collection, processing, and analysis	1 Research Fellow at 25% time	\$13,750
ICF International assistance with recruitment, data collection, and processing	Labor and other direct costs for supporting recruitment, data collection, and processing Task Order# 200-2014-F-59670	\$30,000
Subtotal, Staff, Contractor, and Other Expenses		\$43,750
Total of All Annualized Expenses		\$53,464

A.15 Explanation for Program Changes or Adjustments

Not applicable: this request is for a sub-collection under a generic approval.

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

This is a one-time information collection. Current plans for tabulation and publication of the data from this information collection include the use of thematic analysis to answer our guiding research questions about protective factors and their role in improving the health of transgender youth. These results will be compiled into reports to be circulated internally within CDC DASH

and possibly with CBO sub-contractors as well as submitted as articles to peer-reviewed journals.

Analysis Plan

Upon completion of the interviews, audio-recordings will be transcribed. Transcripts will be imported into NVivo10 qualitative analysis software at CDC where the data set will be managed. Information from the interviewer forms (**Attachment 7**) will also be entered into NVivo10 as part of the data set.

Data from interviews will be analyzed through thematic analysis. Thematic analysis involves the identification of themes in textual data in order to describe concepts, identify patterns, and provide context (Guest, MacQueen, & Namey, 2012). Project staff will develop a codebook of themes for data analysis through review of a subset of the transcripts (e.g., n=10). The codebook will include of a combination of deductive (i.e., a priori codes based on the topics covered in the interview guide) and inductive (i.e., post hoc codes developed through reading the transcripts and noting relevant themes) codes. To develop these codes, study staff will code individual transcripts in this subset separately, and then meet to compare codes and reconcile any points of disagreement. This process will be repeated until there is a high level of reliability in coding of transcripts. Once a codebook has been developed, the remaining transcripts will be coded according to its criteria. The codebook may be revised throughout the coding process as new codes are iteratively discovered throughout data analysis. All codes will be entered into NVivo10. These codes will provide the basis for all subsequent analyses.

Findings will be used to identify gaps in research and program services relevant to transgender youth. Findings derived from qualitative data analysis of these interviews will be reported out via informal briefs, peer-reviewed journal articles, and presentations at national health conferences.

Project Time Schedule

The involvement of ICF International as contractors assisting with recruitment and data collection efforts is funded through a contract modification expires at the end of this fiscal year, thus study activities are slated to begin in Fall/Winter 2016, pending OMB approval. The key events and reports to be prepared as part of this project are listed out in the Gantt Chart below.

Exhibit A.16.1 Gantt Chart of Project Timeline

Activity	Months Out from OMB Approval											
	1	2	3	4	5	6	7	8	9	10	11	12
Recruitment	X	X	X	X								
Interviews		X	X	X	X							
Transcription		X	X	X	X	X						
Data Coding/ Analysis				X	X	X	X	X	X			
Write Scholarly Articles and						X	X	X	X	X	X	X

Briefs												
Dissemination								X	X	X	X	

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

The OMB expiration date will be displayed. We are requesting no exemption.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

References

- Bagley, S. J., Reynolds, W. W., & Nelson, R. M. (2007). Is a "wage-payment" model for research participation appropriate for children? *Pediatrics*, *119*(1), 46-51.
- Beltran, O., Johns, M. M., Armstrong, H., Jayne, P. & Barrios, L. (*in progress*). A systematic review of protective factors experienced by transgender youth.
- Centers for Disease Control and Prevention (CDC). (2015). *Consent, Assent, and Permission Templates*. Retrieved from <http://intranet.cdc.gov/od/oads/osi/hrpo/guides/consent/permtemp.htm>
- Fenway Health. (2010). *Glossary of Gender and Transgender Terms*. Retrieved from http://www.lgbthealtheducation.org/wp-content/uploads/Handout_7-C_Glossary_of_Gender_and_Transgender_Terms__fi.pdf
- Fergus, S., & Zimmerman, M. A. (2005). Adolescent resilience: a framework for understanding healthy development in the face of risk. *Annu Rev Public Health*, *26*, 399-419. doi: 10.1146/annurev.publhealth.26.021304.144357
- Gates, Gary J.(2011). *How Many People are Lesbian, Gay, Bisexual and Transgender?*. UCLA: The Williams Institute. Retrieved from: <https://escholarship.org/uc/item/09h684x2>
- Grossman, A. H., & D'Augelli, A. R. (2006). Transgender youth: invisible and vulnerable. *Journal of Homosexuality*, *51*(1), 111-128.
- Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough?: An experiment with data saturation and variability. *Field Methods*, *18*(1), 59-82.
- Guest, G., MacQueen, K., & Namey, E. (2012). *Applied Thematic Analysis*. Sage Publications.
- Herbst, J. H., Jacobs, E. D., Finlayson, T. J., McKleroy, V. S., Neumann, M. S., Crepaz, N., & Team, H. A. P. R. S. (2008). Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS Behav*, *12*(1), 1-17.
- Kipke, M.D. (1999). *Risks and opportunities: Synthesis of studies on adolescence*. Washington, DC: National Academies Press.
- Kirby, D., & LePore, G. (2007). *Sexual Risk & Protective Factors: Factors Affecting Teen Sexual Behavior, Pregnancy, Childbearing and Sexually Transmitted Diseases. Which Are Important? Which Can You Change*. The National Campaign to Prevent Teen and Unplanned Pregnancy.
- Reisner, S. L., Greytak, E. A., Parsons, J. T., & Ybarra, M. L. (2015). Gender minority social stress in adolescence: disparities in adolescent bullying and substance use by gender identity. *Journal of Sex Research*, *52*(3), 243-256.
- Reisner, S. L., White, J. M., Bradford, J. B., & Mimiaga, M. J. (2014). Transgender Health Disparities: Comparing Full Cohort and Nested Matched-Pair Study Designs in a Community Health Center. *LGBT Health*, *1*(3), 177-184.

- Resnick, M. D., Bearman, P. S., Blum, R. W., Bauman, K. E., Harris, K. M., Jones, J., ... & Udry, J. R. (1997). Protecting adolescents from harm: findings from the National Longitudinal Study on Adolescent Health. *JAMA*, 278(10), 823-832.
- Richardson, G. E. (2002). The metatheory of resilience and resiliency. *Journal of Clinical Psychology*, 58(3), 307-321.
- Rice, M., & Broome, M. E. (2004). Incentives for children in research. *Journal of Nursing Scholarship*, 36(2), 167-172.
- Williams Institute. (2013). *Gender-related Measures Overview*. Los Angeles, CA: The GenIUSS Group.