Feasibility of HIV Behavioral Surveillance for Young MSM

Generic Information Collection Request under 0920-0840

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Supporting Statement Part A

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70. A. JUSTIFICATION

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72. <u>A.1 Circumstances Making the Collection of Information</u> Necessary

73.

74. This request is for sub-collection under a generic approval (Formative Research and Tool Development, OMB Control No. 0920-0840, exp. 02/29/2016), for a one-year pilot project to identify the most appropriate sampling methods for reaching men who have sex with men (MSM) between 13 and 17 years of age for ongoing HIV behavioral surveillance.

75.

76. More than 30 years since the first reported cases of AIDS, HIV infection continues to exact a tremendous toll in the United States. CDC estimates that approximately 50,000 new HIV infections occur each year and 1.2 million Americans are living with HIV in this country (CDC, 2012; Prejean et al., 2011). MSM, particularly those who are young and from a minority racial or ethnic group, remain disproportionately affected by HIV. Between 2008 and 2010, there was a 12% increase in new infections among MSM overall, driven by a 22% increase among MSM aged 13-24 years. This risk was especially notable for young black MSM. In 2010, the greatest number of new infections among MSM occurred in black MSM aged 13-24 years. Young black MSM accounted for 45% of new HIV infections among young MSM overall (CDC, 2012).

77.

78. Data from the National HIV Behavioral Surveillance System (NHBS) among MSM in 2011 shows a high prevalence of HIV among young black MSM. In the 18-19 year age group, 13% of black MSM were HIV-positive compared to only 2% of white MSM. In the 20-24 year age group, 24% of black MSM were HIV-positive compared to 5% of white MSM. Although the timing of infection relative to diagnosis is often unclear, many individuals who are asymptomatic are not diagnosed with HIV infection until years after they are infected. The high prevalence of infection in young adults suggests that at least some of these infections may have occurred during the adolescent years.

79.

80. Research with adolescent and emerging adult MSM is necessary to address the growing HIV epidemic in this population; inferring results of studies of older MSM to young MSM is insufficient for a number of reasons. First, in the United States, there are typically significant developmental changes in one's life around age 18 (Arnett, 2000). At this time, many young people move out of their parents' homes and other important life transitions are occurring. Second, brain development continues through late adolescence, and capacities for behavioral and emotional

regulation are still relatively immature (Somerville, Jones, and Casey, 2010). Similarly, owing to brain development, drug and alcohol consumption during adolescence can have differential and more deleterious effects on behavior and brain injury than consumption in adulthood (Spear, 2002). Third, recall of past sexual events is subject to a number of forms of recall bias, and retrospective accounts from older MSM may be biased. Fourth, the rapid change in the social status of homosexuality (Loftus, 2002) means even accurate retrospective reports of an adult may not match the current experiences of an adolescent. These developmental factors and the limitations of using data from older MSM suggest that accurately understanding HIV risk and resilience in young MSM requires the inclusion of participants under the age of 18.

81.

82. NHBS is CDC's ongoing national HIV behavioral surveillance system, the purpose of which is to monitor the prevalence of and trends in behaviors that lead to acquisition of HIV infection. NHBS currently monitors the risk behaviors of three populations at high risk for HIV infection: adult MSM, injection drug users, and heterosexuals. However, there is presently no surveillance system to monitor risk behaviors among MSM under the age of 18 years. CDC's previous survey of young MSM, The Young Men's Survey (YMS) which employed venue-based sampling of young MSM between the ages of 15-22 years over a four-year period, was conducted more than 15 years ago, enrolling 644 MSM aged 15-17 years across seven sites. Other existing surveillance systems funded by CDC that focus on youth, such as the Youth Risk Behavior Surveillance System (YRBSS) do not specifically target MSM. The majority of other studies of MSM focus on men older than 18 years (Mustanski, 2011), whereas the few that focus on MSM under age 18 have relied on relatively small samples with unknown representativeness, including convenience samples, snowball samples, or samples recruited from specific locations frequented by young MSM to access HIV-related services (Dudley et al., 2004).

83.

84. Sampling constraints have plagued research on young MSM for decades because there is no established sampling frame to determine external validity. Whether sampling methods that are most often used with adult MSM (e.g., venue-based sampling) will be effective with young MSM is unknown. There are several factors that present challenges to sampling young MSM. Many large-scale studies of youth populations, including CDC's own YRBSS, use school-based sampling methods. Although these representative school-based samples have included a few questions about sexual orientation or same-sex behaviors (CDC, 2011; Garofalo et al., 1998), they have focused predominantly on health concerns other than HIV. Sampling young MSM in schools to collect information on HIV risk behaviors is not an option because of the challenges of

accessing and identifying the target population within the school environment.

85.

Sampling youth outside of school settings, particularly 86. youth who are members of marginalized or stigmatized groups, is challenging as well because these groups are hard to reach. For example, very few venues exist where young MSM congregate and where study recruitment could take place. Moreover, venues catering to adult MSM often explicitly prohibit persons under age 18 from entering, thus adult MSM venues are not appropriate venues from which to recruit young MSM. Also, given the stigmatized nature of same-sex sexual behavior, identity, or attraction among youth, young MSM may be less likely than adult MSM to form communities centered on these shared characteristics or disclose their status as young MSM to their peers. Therefore, they may be less well connected to other MSM when compared to adult MSM. Young MSM are also at an earlier developmental stage both in a general sense and with respect to their sexuality than adult MSM, and may or may not have come to terms with or disclosed same-sex identity, behavior, or attraction to peers, family members, or other adults in their lives. Because of these factors, novel approaches to sampling and recruitment may be necessary to effectively reach this population.

87.

88. The NHBS-YMSM pilot will serve as a formative assessment of the feasibility of a national HIV behavior surveillance system for young MSM, and is designed to identify the most appropriate method(s) for sampling MSM 13 to 17 years of age. The information collected on young MSM from this pilot will be used to decide whether ongoing monitoring of this population could be conducted and if so, whether to incorporate this age group into the adult NHBS-MSM cycle or establish an additional NHBS cycle. This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1).

89.

90. A.1.1 Privacy Impact Assessment

91.

92. The only information in identifiable form collected for the NHBS-YMSM pilot project is date of birth. Date of birth will be stored, along with a study identification number, with data collected for the proposed formative research both locally and at CDC. Date of birth is being collected to determine eligibility for NHBS-YMSM data collection, which is limited to persons between 13 and 17 years of age. In addition, date of birth is collected for quality control purposes. Date of birth for sampled participants will be compared across NHBS-YMSM interviews and HIV tests to ensure that information is collected on the correct person and that duplicate information is not collected. Other

than date of birth, information in identifiable form will not be included in any NHBS-YMSM data collection instruments or systems, including test results.

93.

94. Date of birth will be sent to CDC, but will not be shared beyond the CDC team conducting the data collection (i.e., it will not be included in analysis datasets). Specimens, test results and behavioral assessments will be linked using the Study ID number and the interview date. To protect the anonymity of those interviewed, assent/consent to participate will be provided verbally by participants. No information in identifiable form other than date of birth will be collected during the NHBS-YMSM behavioral assessment. Therefore, individuals cannot be indirectly identified through NHBS-YMSM data.

95.

96. Although individuals will not be able to be directly or indirectly identified through the data stored at CDC, project areas will collect personal identifiers (first name or nickname, phone number and/or email address) to allow scheduling of NHBS-YMSM screening and data collection activities. This information will only be available to grantee staff, specifically, the Program Coordinator and Study Investigators, and will be stored in a computer which the Program Coordinator will be responsible for securing. For one of the sampling methods that will be tested through the pilot, persons interested in participating in the study will enter personal identifiers (first name or nickname, phone number and/or email address) on an internet form; however, no internet protocol (IP) address will be collected or stored with the contact information entered by potential participants.

97.

98. Personal identifiers will be maintained by the project areas under strict access controls. Only authorized project area staff will use the names and contact information in the project area database to contact and recruit sampled persons. In the project areas, data collected for the proposed research will be stored separately from personal identifiers used for recruitment. When the respondent has completed participation, or by 02/01/2015, whichever is earlier, project areas will destroy the contact log page containing the first names or nicknames, phone numbers and/or email addresses of the participant. Project areas will not transmit personal identifiers to CDC, nor will CDC staff have access to them.

99.

100. Qualitative methods, specifically key informant and focus group interviews, will be conducted before launching the pilot data collection, to gather information to guide local implementation of the pilot. To protect the anonymity of key informants and focus group participants, assent/consent to participate will only be provided verbally by participants and

interviews will not be video- or audio-taped. The interviewer or moderator will take handwritten notes on responses during key informant and focus group interviews and will not record any personally identifying information in the written record. The notes will be stored without identifiers in a locked filing cabinet inside a locked office in the project area. Only authorized persons will have access to the notes, and they will not be transmitted to CDC.

101.

assessment will be collected via a handheld computer. The security of data on handheld, desktop, or laptop computers used for the pilot will be maintained through training, password protection, encryption, and controlling access to hardware. All authorized NHBS-YMSM project staff will complete a security and confidentiality training and sign a statement designed by each site indicating their understanding of security and confidentiality policies. NHBS-YMSM project staff will also receive training from CDC on how to protect the security and confidentiality of the information collected.

103.

104. Grantees will transmit data files without identifiers to a CDC contractor, ICF International, through the Data Coordinating Center (DCC) data portal, a secure web-based mechanism. The data transfer methodology is compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as with OMB, HHS, and CDC Certification and Accreditation Guidelines outlined in NIST SP 800-37 (Guide for the Security Certification and Accreditation of Federal Information Systems). The DCC has received approval through the Information Technology Certification and Accreditation process (Attachment 2).

105.

106. A.1.1.1 Overview of the Data Collection System 107.

108. The goal of this pilot project is to evaluate the feasibility of incorporating MSM between 13 and 17 years of age into ongoing HIV behavioral surveillance.

109.

110. The objectives of this pilot project are the following:

111.

112. 1) To determine the most effective sampling method(s) to reach MSM between 13 and 17 years of age, measured by the likelihood of each method achieving the desired sample size during the data collection period.

113.

114. 2) To ascertain the feasibility of implementing each sampling method, measured by several factors including the

organizational, technical, and operational challenges associated with each method, implementation costs, and the acceptability of each method among the target population.

115.

116. 3) To evaluate the need to conduct ongoing HIV surveillance among MSM -between 13 and 17 years of age by examining data collected for the pilot related to HIV risk behaviors, HIV seroprevalence, HIV incidence, and other HIV-related outcomes.

117.

118. Because the pilot project is intended to assess the feasibility of incorporating the 13-17 year old age group into the adult NHBS-MSM cycle or establishing an additional NHBS cycle, data collection activities for the pilot will closely parallel the standard NHBS data collection. A total of three health department grantees (Chicago Department of Public Health, Philadelphia Department of Public Health, and New York City Department of Health and Mental Hygiene) are funded to conduct the pilot from among the 20 NHBS grantees nationwide.

119.

120. Based on a review of the relevant literature and consultation with a number of subject-matter experts, three sampling methods were selected to be evaluated for their effectiveness in reaching young MSM to conduct a behavioral assessment and HIV testing: respondent-driven sampling (RDS), venue-based sampling (VBS), and Facebook sampling (FBS). RDS is used in the injection drug user (NHBS-IDU) and heterosexual (NHBS-HET) cycles of NHBS and VBS is currently used in the NHBS-MSM cycle. FBS has not been used for NHBS recruitment. The target population for this formative study will be males aged 13 to 17 years living in the participating metropolitan statistical areas (MSAs), who have ever had any sexual contact with another male or self-identify as gay or bisexual or report same-sex sexual attraction, are able to understand and respond to interview questions in English, and have the capacity to provide informed assent for participation.

121.

122. Before implementing any of the sampling methods, each project site will conduct preliminary research activities for 2 to 3 months in order to guide local implementation of NHBS-YMSM to ensure successful data collection. These activities include reviewing secondary data sources, observations by project site staff of potential field sites and venues, and conducting key informant interviews and focus groups.

123.

124. The interview guides for key informant and focus group interviews (Attachments 7 and 8), which will be administered by a project area staff member, are semi-structured, allowing for detailed and in-depth discussions. Information collected through these semi-structured interviews may be used to validate findings

from the secondary data review or to explore issues that were raised by expert consultants or observations of local project staff.

125.

126. Key informants will serve as "cultural experts," who will be asked to provide insight into the context of HIV risk behavior among young MSM locally, as well as how to best recruit this population for the pilot. Although good key informants may not know everything there is to know about young MSM in the MSA, they should be able to contribute to the understanding of how best to approach potential participants and anticipate problems that NHBS-YMSM staff may encounter in the field. Examples of key informants include: gay community leaders, owners of local businesses that cater to young MSM, persons doing outreach work among young MSM, members of the local young MSM community, and researchers whose work has a local focus on young MSM. Key informants who meet the NHBS-YMSM eligibility criteria may take part in the NHBS-YMSM behavioral assessment and optional HIV testing.

127.

128. Focus groups will be conducted with several individuals (up to 10) at a time, under the direction of a moderator. Participants in focus group discussions will be recruited from within the MSA. These interviews can provide general information about local context relevant to young MSM or specific information needed for recruitment and not otherwise available. Focus group participants may include community stakeholders regardless of their sexual identity (e.g., owners of local businesses that cater to young MSM, gay community leaders, and staff in organizations that serve either local young MSM populations or the gay community) and young MSM themselves.

129.

130. Key informants and focus group participants will be identified through organizations and individuals working with young MSM. Focus group participants who meet the NHBS-YMSM eligibility criteria may take part in the NHBS-YMSM behavioral assessment and optional HIV testing. First names or nicknames, phone numbers and/or email addresses of potential key informants and focus group participants will be collected by the referring individual and shared with NHBS-YMSM local staff. The local staff will make contact and ask the potential key informants and focus group participants to come to the study site for an interview or focus group. When the key informant or focus group participant comes to the study site, the interviewer or moderator will first obtain informed assent/consent by reading the assent/consent form (Attachment 13) and obtaining verbal agreement to participate. Key informant interviews and focus groups will not be video- or audio-recorded. The interviewer or moderator will take

handwritten notes on responses and will not record any personally identifying information in the written record.

131.

132. When the key informant interview or focus group has been completed, the notes will be stored without identifiers in a locked filing cabinet inside a locked office. Only authorized persons will have access to the notes. Notes will be retained until 2/1/2015, when they will be destroyed.

133.

134. Testing of the three sampling methods will begin after the key informant and focus group interview data have been analyzed for information such as the size of young MSM networks and potential seeds (to inform local implementation of RDS), the specific venues frequented by young MSM (to inform local implementation of VBS), and suggestions for content and presentation of online banner advertisements (to inform approaches for FBS).

135.

136. RDS is a modified chain-referral strategy similar to snowball sampling. RDS will start with a limited number (5-10) of "seeds" or individuals who meet all eligibility criteria for NHBS-YMSM and serve as the starting point for chain-referral sampling. Seeds will be chosen by referrals from people who know the local young MSM, or by staff outreach in areas identified through preliminary research. These seeds will complete the eligibility screener, behavioral assessment, and optional HIV testing, and will then be trained to recruit up to 5 other young men in their social network who also meet the eligibility criteria for NHBS-YMSM (the Recruiter Training Script is included as Attachment 3). This recruitment process will continue until the sample size has been reached. RDS has been found to be effective for recruiting populations that are "hidden" and that are connected by social networks and ties (Heckathorn, 1997). It has also been used successfully to recruit youth for several research studies (Gwadz et al., 2010; Kogan et al., 2011; Mustanski et al., 2013).

137.

138. VBS is a sampling strategy that utilizes venues within a community to obtain the desired sample. A venue is an area, location, or building where young men can be approached and recruited to participate in NHBS-YMSM. Venues may include dance clubs, retail businesses, cafes and restaurants, health clubs, social and religious organizations, school group meetings, high-traffic street locations, parks, beaches, and special events such as gay pride festivals, raves, and circuit parties. Support groups for HIV-infected persons and clinical or other settings which are exclusively for providing medical care, mental healthcare, social services, or HIV/STD diagnostic services will be ineligible for consideration as venues.

In each project site, a team of staff members familiar with 140. the community will conduct preliminary research to construct an initial "universe" of venues frequented by young MSM. Staff members will then assess the venues and day-time periods in the initial "universe" to determine which have a sufficient number of eligible young MSM for conducting NHBS-YMSM recruitment. These venues and day-time periods will be included on the monthly sampling frames used to randomly select venues and day-time periods for recruiting participants. Young men will be recruited to participate in NHBS-YMSM at randomly selected venues during selected day-time periods. At these recruitment events, staff will count venue attendees, approach young men to ask them to participate in the study, interview eligible young men, and offer optional HIV testing. Although project staff will initially perform these activities in sequence, sampling frames will be continually updated throughout the project cycle. VBS is a method that has proven successful in obtaining large and diverse samples of MSM and has also been used successfully to recruit young MSM ages 16-21 years of age (Diaz et al., 2001; MacKellar et al., 1996; MacKellar et al., 2005; Muhib et al., 2001; Sanchez et al., 2006; Stueve et al., 2001).

141.

142. FBS is a strategy that utilizes Facebook to recruit participants. Internet websites have been used successfully to recruit participants from a variety of populations, including MSM, and one of its primary benefits is the ability to reach segments of the MSM population that would be more difficult to reach with other methods (Elford et al., 2004; Fernandez et al., 2004; Grov et al., 2013; Parsons et al., 2013; Raymond et al., 2010). In general, recruitment via Facebook involves placing advertisements targeting groups that meet specific demographic and geographic criteria. In the proposed project, recruitment ads will target all young men aged 13 to 17 years who indicate in their Facebook profile that they are interested in [attracted to] other men who live within specific zip codes.

143.

144. Potential participants will click on the ad, which will take them to a landing page which has more information about the study and provides study investigators' contact information. The page will also have a place for potential participants to enter their first name or nickname, phone number and/or email address, which will allow NHBS-YMSM local staff to follow-up and conduct eligibility screening by telephone. These personal identifiers will be maintained by the project areas under strict access controls. In the project areas, data collected for the proposed research will be stored separately from personal identifiers used for recruitment. When the respondent has completed participation, or by 02/01/2015, whichever is earlier, project areas will

destroy the contact log page containing the first names or nicknames, phone numbers and/or email addresses of the participant. Project areas will not transmit personal identifiers to CDC, nor will CDC staff have access to them. No IP addresses will be collected along with contact information potential participants enter on a web page during FBS.

145.

146. If telephone screening indicates a potential participant is likely to be eligible, project staff will schedule an appointment for the participant to come to one of the NHBS-YMSM field sites to complete an in-person eligibility screener. The initial eligibility screening by phone will be conducted to reduce the number of ineligible individuals who come to the study field site. Even if a potential participant is determined to be eligible by phone, an in-person eligibility screening will be conducted to verify the information and connect the eligibility responses to the behavioral assessment and HIV testing data.

147.

148. Eligible young men who assent will participate in a one-time structured behavioral assessment interview. Project staff will collect behavioral assessment data using the behavioral assessment form (Attachment 6) in a software application loaded onto handheld computers. All data will be encrypted and computers used for data collection will be password protected so that unauthorized users will be unable to view, export or modify collected data. The data will be transmitted to CDC through a secure portal. Electronic data collected for the proposed formative research will be maintained indefinitely at CDC.

149.

assessment will be offered anonymous HIV testing. The testing component of NHBS-YMSM is voluntary. Young men who agree to participate in the testing component of NHBS-YMSM will be provided with information about HIV testing. In accordance with local procedures and practices, project sites may offer rapid or laboratory-based HIV testing to participants. The purpose of testing is to estimate HIV prevalence among MSM 13 to 17 years of age who participate in NHBS-YMSM. HIV test results will be returned to participants by a trained counselor during a scheduled counseling visit or shortly after the time of testing if a rapid test is used.

151.

152. All participants who test positive for HIV will be actively linked to appropriate medical care and HIV case management services at the time they receive their test results. Active linkage to care in NHBS-YMSM will involve an increased level of assistance by project staff members (e.g., scheduling appointments, providing transportation) to link HIV-positive participants to medical care and other supportive services. At

each NHBS-YMSM site, local protocols will be developed for active referrals and linkage to HIV care. These protocols must consider that HIV-positive youth may need additional assistance and support above and beyond protocols for referrals and linkage to HIV care developed for adult populations. In addition, participants should be offered the number of a suicide prevention or other crisis counseling hotline in case of distress about preliminary positive or confirmed positive HIV test results. Study staff may not share the participant's name or other personally identifying information for linkage to care or report this information to the state or local health department HIV surveillance unit.

153.

154. The feasibility of incorporating MSM between 13 and 17 years of age into ongoing HIV behavioral surveillance will be evaluated using data from a number of project components. First, CDC staff will examine data on the ability of each sampling method to enroll 300 young men per site who meet the NHBS-YMSM eligibility criteria, including the time that it takes to reach the enrollment goal. Second, CDC will consider organizational, technical, and operational challenges associated with each method, implementation costs, and the acceptability of each method among the target population. Third, CDC will analyze data on the response rates during each step in the recruitment process as well as the rate of agreement to HIV testing. CDC will monitor the demographic characteristics of participants recruited through each sampling method to determine which sub-populations of young MSM are reached through each. Finally, CDC will evaluate the behavioral assessment data to assess its potential to contribute to possible future ongoing monitoring of HIV risk among young MSM and to inform HIV prevention efforts.

155.

156.

157. A.1.1.2 Items of Information to be collected

158.

159. Seven data collection instruments (forms) are associated with the proposed formative research:

160. Two instruments, for the key informant and focus group interviews, are to be used for preliminary data collections needed, regardless of sampling method, to guide local implementation of the study so as to ensure successful data collection from young MSM.

161.

162. Three forms are designed to collect data related to implementation, the enumeration interview form used to assess the suitability of venues for the VBS method, the landing page used to collect contact information to allow recruitment for FBS, and the recruiter debriefing instrument used to facilitate non-response bias analysis for RDS.

164. The remaining two instruments will be used whether young MSM are sampled through VBS, FBS, or RDS. They are the screener to determine eligibility and the behavioral assessment instrument, which will be used to collect information about the characteristics and HIV risk behaviors of participating young MSM.

165.

166. Key informant interview (VBS, RDS, and FBS)

167.

168. The key informant interview guide is the first of the instruments that will be used for preliminary data collection to guide implementation. Key informant interviews are semistructured to allow for detailed and in-depth discussions. Information collected through key informant interviews can be exploratory in nature (e.g., the locations where young MSM meet and socialize, and the demographic and social network characteristics of local young MSM) or focused on specific topics (e.g., the best days and times to recruit at venues and barriers to recruitment or effective Facebook banner ad characteristics). The interview guide for key informant interviews is located in Attachment 7.

169.

170. Focus group interview form (VBS, RDS, and FBS)

171.

that will be used to collect information to guide implementation. Similar to key informant interviews, focus group interviews are semi-structured to allow for detailed and in-depth discussions. These interviews can provide information about general topics such as means of recruiting young MSM who do not identify as being gay to participate in the study, and specific information needed for recruitment and not otherwise available, such as social and sexual network characteristics of young MSM in the community; where local young MSM congregate and what alternative venues might be utilized for recruitment that aren't easily identified through a review of secondary data; and which websites are frequented by local young MSM). The interview guide for focus groups is located in Attachment 8.

173.

174. Enumeration Form (VBS only)

175.

176. The enumeration forms will be used to collect data on the demographic characteristics and behaviors of young men attending a venue to determine if a sufficient number of eligible young MSM attend the venue to designate it as a recruitment site.

Attachment 9 includes the enumeration interview form and corresponding instructions.

178. Landing Page (FBS only)

179.

180. The landing page (Attachment 10) will link to the Facebook advertisement and will include more information about the NBHS-YMSM study for potential participants. Interested men will be asked to enter their contact information on an internet form accessed through the landing page, so that NHBS-YMSM staff can contact them to conduct a telephone eligibility screener and schedule the in-person eligibility screener, behavioral assessment, and optional HIV testing. Contact information for investigators at the local NHBS-YMSM site will also be listed on the landing page, so that interested participants may call to undergo eligibility screening and schedule their own appointments or ask questions.

181.

182. Recruitment Debriefing (RDS only)

183.

184. The peer recruitment debriefing instrument will collect data to measure non-response bias by asking the participant about any individuals who refused the coupons to participate in the study they were offered. The items in the peer recruitment debriefing instrument (Attachment 4) include the number of coupons the recruiter has distributed, whether anyone has refused the coupons, the race/ethnicity and age of those refusing coupons, and the reason for refusal.

185.

186. Eligibility Screener (VBS, RDS, and FBS)

187.

188. The eligibility screener will collect data on eligibility to participate in NHBS-YMSM. Data collected using the eligibility screener will include age calculated from date of birth; race/ethnicity; previous participation in the NHBS-YMSM pilot; county of residence and length of time residing there; gender; whether the respondent has ever had oral, anal, or other sexual contact with another male; whether the respondent identifies as gay or bisexual, and whether the respondent is sexually attracted to other males (Attachment 5).

189.

190. Behavioral Assessment (VBS, RDS, and FBS)

191.

192. The NHBS-YMSM behavioral assessment will collect data on the characteristics and HIV risk behaviors of MSM aged 13-17 years, including demographics, social networks and social support, sexual behaviors, alcohol and drug use history, HIV testing experiences, health conditions, experiences with violence and bullying, experiences of stigma and discrimination, and exposure to prevention activities (Attachment 6)

194. In the course of implementing the study, project staff will maintain forms to document HIV specimens sent to the laboratory (including study identification number); counts of attendees at venues; and pre-implementation, implementation, and operational/maintenance costs associated with each sampling method; these forms will not be used to collect data from the public.

195.

196. Data collected through NHBS-YMSM, both locally and at CDC, will be stored and accessed by a study identification number. Other data collected through NHBS-YMSM, while sensitive, are not personally identifying; these questions are included in Attachment 6. The sensitive information collected will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person.

197.

198.

- 199. A.1.1.3 Identification of Websites and Website Content Directed at Children Under 13 Years of Age 200.
- **201.** This information collection does not involve websites or website content directed at children less than 13 years of age. **202.**
- 203. A.2. Purpose and Use of Information Collection 204.
- 205. The purpose of the NHBS-YMSM pilot is to serve as a formative assessment of the feasibility of a national HIV behavior surveillance system for young MSM. The pilot is designed to identify the most appropriate method(s) for sampling MSM 13 to 17 years of age. The information collected on young MSM from this pilot will be used to decide whether ongoing monitoring of this population could be conducted and if so, whether to incorporate this age group into the adult NHBS-MSM cycle or establish an additional NHBS cycle. Including young MSM in existing surveillance efforts, if feasible, would help to characterize the scope of the HIV epidemic among young MSM, and in turn help guide prevention efforts targeting this population.

- 207. A.3. Use of Improved Information Technology and Burden Reduction 208.
 - 209. Interview data will be collected on password-protected encrypted portable computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland. Provision of electronic data collection software will help to reduce the burden of data collection on grantees conducting NHBS-YMSM. The use of an electronic questionnaire may reduce the burden on respondents by improving comprehension and reducing the amount of time needed to complete the behavioral assessment, as compared with a paper-administered assessment.

211. CDC will conduct training and site visits to provide instructions and technical assistance on how to use the software, conduct the behavioral assessment, archive the collected data, and transfer the data. CDC will also provide training to the participating health department and detailed written instructions on methods for conducting the study. CDC will require local NHBS-YMSM staff providing supervision on the project to monitor interviewers regularly. Automated edit checks will be built into the computer software programs as an additional quality control measure.

212.

Provision of electronic data collection hardware and 213. software, training and technical assistance will help to reduce the burden on grantees conducting NHBS-YMSM. Transfer of data collected electronically will eliminate the need for data entry at the local sites. An evaluation of supplemental surveillance data using electronic data collection has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

214.

215. For VBS, a computer program is used for 2-stage random sampling of venues and day-time periods within venues (described more fully in Part B). The computer program will ensure that selections are made randomly. This program also records the selections that were made, and can generate a monthly calendar of recruitment events. The information generated from this program may then be used to weight the data for probability of selection.

216.

217. Data linking recruiters and recruits for RDS will be entered directly into a computer program, called "Respondent Driven Sampling Coupon Manager" (RDSCM). By entering data directly into the computer, the efficiency of data collection is improved as compared to using paper and then entering data. The RDSCM program also reduces the time and effort to validate coupons and track payments of tokens of appreciation. During a participant's visits to the field site, data can be called up efficiently through use of search terms, such as by coupon number. With logic checks and range values programmed in, the quality of the data is improved. Data from RDSCM linking recruiters and recruits is also used in analysis and weighting to produce adjusted estimates.

219. For FBS, Facebook will generate automated reports that will allow local NHBS-YMSM staff to monitor the effectiveness of the recruitment method and the composition of the recruited sample. Combined with data from the portal, local NHBS-YMSM staff will be able to calculate response rates and make adjustments to the Facebook recruitment effort as needed.

220.

221. CDC Division of HIV/AIDS Prevention, (DHAP) has implemented the use of handheld and laptop devices for other national surveillance systems. All health departments participating in NHBS-YMSM are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

222.

223. The purpose of the Data Coordinating Center (DCC), managed by ICF International through a contract with CDC, is to implement a data management system to provide NHBS-YMSM project areas with a secure web-based data portal system through which project areas can easily submit data to CDC, revise submitted data sets, and receive final data from CDC. The system also allows the project areas and CDC staff to track critical respondent and HIV testing activities. The system also incorporates a secure web-based interface that allows CDC and project area staff members to submit data, track project area activities, retrieve data sets and reports. This will help reduce project management burden at the project area and streamlines the data collection and management process.

224.

225. <u>A.4. Efforts to Identify Duplication and Use of Similar</u> Information

226.

227. We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects or maintains data on HIV risk behavior data from MSM aged 13 to 17 years. Although NHBS collects similar data elements as are being proposed for NHBS-YMSM, NHBS currently only monitors adult MSM. The information collected through NHBS-YMSM will be used to determine whether to incorporate the 13-17 year old age group into the adult NHBS-MSM cycle or establish an additional NHBS cycle.

228.

229.

230. <u>A.5. Impact on Small Businesses and Other Small Entities</u>

231.

232. No small businesses will be involved in this data collection effort.

233.

234.

235. A.6. Consequences of Collecting the Information Less Frequently

237. The proposed project involves a one-time data collection. There are no legal obstacles to reducing burden.

238.

239.

- 240. A.7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5
 - **242.** This request fully complies with the regulation 5 CFR 1320.5.

243.

244. <u>A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency</u>

245.

- 246. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A Federal Register Notice for the umbrella collection was published on August 2, 2012 (Vol. 77, No. 149, pp. 4604-46095, expiration date 2/29/2016).
 247.
- 248. A.9. Explanation of Any Payment or Gift to Respondents 249.
 - 250. Participants will be given approximately \$25 in cash for participation in the behavioral assessment and \$25 for taking a voluntary HIV test as a token of appreciation for participation; the specific amount will be determined by grantees based on local standards. If local regulations prohibit cash tokens of appreciation, equivalent tokens may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

251.

252. In the RDS methodology, participants receive a token of appreciation for participating as a respondent and a reward for successfully recruiting one or more of their peers. Recruiter rewards are approximately \$10 for each of up to five peer referrals, which is standard for RDS studies (Heckathorn et al., 2002; Ramirez-Valles et al., 2005; Wang et al., 2004). As with the behavioral assessment and testing incentives, if local regulations prohibit providing cash, an equivalent token of appreciation may be offered in the form of gift certificates or cash cards.

253.

254. 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), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..."

256. The use of token of appreciation for participation in NHBS-YMSM is appropriate because the project seeks to conduct surveys with a hard-to-reach and highly selective population and ask participants highly sensitive questions about issues such as sexual behavior and substance use (Kulka, 1995). Because the behavioral assessment takes approximately 40 minutes to complete, to increase response rates, eligible persons are offered a token of appreciation to participate. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest.

257.

258. The need for and amount of the remuneration is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions in the participating areas offer similar tokens of appreciation. Thus, NHBS-YMSM would be competing with local researchers who do offer remuneration. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (MacKellar et al., 2005; Thiede et al., 2009). Providing remuneration to NHBS-YMSM respondents is critical to achieve acceptable response rates.

259.

260. Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), and the Medical Monitoring Project (OMB 0920-0740, exp. 05/31/2015) all of which ask questions similar to those in NHBS-YMSM and have a similar length of time for completing the behavioral assessment. In these other projects incentives were used to help increase participation rates; participants were offered approximately \$25, to be provided when they completed the survey. Other studies have also found that incentives modestly improve response rates (Shaw et al., 2001).

261.

262. <u>A.10. Assurances of Confidentiality Provided to Respondents</u> 263.

are anonymous (neither names nor social security numbers are collected). Full date of birth will be collected by NHBS-YMSM for two reasons: to ensure that participants meet the age eligibility criteria for participation in the study, and for identifying potential duplicate records or participants who have participated more than once per cycle. Records that have exactly the same date of birth will be compared on date of the behavioral assessment and other demographic information such as race/ethnicity and education; investigators will determine whether a record is a duplicate or whether a respondent has already participated during

the cycle based on how closely this information matches. Full date of birth will be sent to CDC, but will only be available to CDC staff overseeing data collection (i.e., data of birth will not be maintained in analysis datasets).

265.

266. In the project areas, data collected for the proposed research will be stored separately from personal identifiers used for recruitment. Other data that will be collected through NHBS-YMSM, while sensitive, are not personally identifying. Project areas will not transmit personal identifiers to CDC, nor will CDC staff have access to them. Data collected through NHBS-YMSM, both locally and at CDC, will be stored and accessed by a study identification number.

267.

NHBS-YMSM is covered by an Assurance of Confidentiality for 268. HIV/AIDS surveillance data (Attachment 11). The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

269.

270. A.10.1 Privacy Impact Assessment

271.

272. The NHBS-YMSM behavioral assessment will be conducted by trained NHBS-YMSM staff in a private location where the questions and responses cannot be overhead by others. NHBS-YMSM data will be transmitted to CDC via the secure system described above known as the DCC. Encryption security for all NHBS-YMSM data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

273.

274. A number of required protections ensure the security of the data on the data collection computers. The tablet computers and laptop computers will be used solely for NHBS-YMSM data

collection activities. NHBS-YMSM data will be encrypted when stored on a tablet device or laptop. Computers will be protected by using a coded password only known by authorized NHBS-YMSM project staff. NHBS-YMSM data will be deleted from the laptop computers after they are uploaded to the main secured database. The tablet and laptop computers must be kept with the staff at all times in the field; the computers will be collected and secured by the field supervisor after return to the local NHBS-YMSM office. When not in use in the field, the computers are to be locked in a drawer or an office.

275.

276. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the document "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs" available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuid elines.pdf).

277.

278. NHBS-YMSM interviewers and data managers will undergo annual security and confidentiality training consistent with the quidelines set forth in the document ""Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs" available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuid elines.pdf). CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement, and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award. Any NHBS-YMSM data maintained at CDC that are released to persons other than project staff will not include full date of birth.

279.

280. The informed assent/consent process for respondents may be fulfilled by obtaining oral assent/consent. All sites must obtain assent/consent for all study activities. Model assent/consent

forms for are included in **Attachment 13**. These forms may be modified as required by a project area Institutional Review Board (IRB). Assent must be obtained separately for key informant interviews, focus group interviews, the behavioral assessment and HIV testing. Participants may elect to complete the behavioral assessment and not be tested; however, they may not be tested without completing the behavioral assessment (those persons who only want an HIV test may be given information on where to seek an HIV test elsewhere). Respondents will be informed that data collected from them for NHBS-YMSM will be kept private and secure and that the data will be reported in aggregate format.

281.

282. Project Determination for NHBS-YMSM is currently underway. The Principle Investigator is requesting "research, non-engaged" status for NHBS-YMSM, as CDC staff is not directly engaged with human subjects in connection with this project. If this request is approved, the protocol will not be reviewed by CDC's IRB. Each participating health department will be required to obtain local IRB approval before data collection.

283.

284. A.11. Justification for Sensitive Questions

285.

HIV can be transmitted from person to person through sexual 286. contact and the sharing of HIV contaminated needles and syringes. In addition, HIV-infected persons with higher HIV viral loads may be at increased risk of transmitting the virus to others. modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use, which NHBS has been approved to collect. Accordingly, the proposed project will also collect these data. As with NHBS' data collection, this formative research data collection will also request sensitive information relating to race/ethnicity, STD and HIV diagnosis and testing, mental health conditions such as depression, history of suicide attempt, incarceration history, alcohol and drug use, experience of violence and bullying, and experience of stigma and discrimination. In addition, geographic information such as zip code and census tract are collected to permit spatial analysis of the data to understand the geographic distribution of disease and risk.

- **288.** Although the information requested from participants is highly sensitive, the purposes of NHBS-YMSM cannot be accomplished without their collection. Collection of the data will be used to determine
- **289.** whether participants are willing to answer sensitive questions and whether their responses yield useful information. **290.**

291. The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in NHBS-YMSM to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

292.

- Nearly all questions allow for responses of "don't know" or "refuse to answer."
- Assent/consent scripts make it clear that the behavioral assessment is sponsored by CDC and the local health department and that the information will be put to important uses.
- Toll-free phone numbers will be provided in case the respondent has questions about the study.
- The behavioral assessment is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for information is explained.
- Assurances about the privacy and confidentiality of the data will be reiterated.
- The use of handheld or portable computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).
- The payment of a token of appreciation indicates clearly to the respondent that the information is important to the study sponsors.
- 293. All interviews will be conducted by trained field staff in a private location during established operating hours at local field site locations (RDS and FBS) or a venue (VBS). Interviewers will be trained to administer the assent script and all interview questions by reading each item verbatim, thus ensuring that all respondents receive the same information for the assent and each question. No interviews will be conducted without the verbal assent of the respondent.

294.

295. Social security numbers will not be collected from respondents.

296.

297. No data will be collected from agencies regarding their policies, performance data or other practices.

298.

299. A.12.Estimates of Annualized Burden Hours and Costs 300.

301. A.12.A. Estimated Annualized Burden Hours 302.

303. The estimate of annualized burden hours for this sub collection is 1715 hours; details are provided in exhibit A.12.A. For preliminary research activities, 60 individuals are expected to participate in key informant interviews and each interview is

expected to take 60 minutes. For the focus groups, 60 individuals are expected to participate and each focus group will be approximately 60 minutes. For the enumeration interview (VBS preliminary research activities only) 100 individuals are expected to participate and each interview will last approximately 2 minutes.

304.

305.

306. VBS sampling will occur in one project area. At this site, approximately 470 individuals will be approached to participate in the NHBS-YMSM study in a 12-month period. We expect approximately 20% of young men to refuse the approach. Of the approximately 376 individuals who accept the approach, a screener will be used to determine eligibility by assessing a respondent's race/ethnicity, age, previous participation, county of residence and length of time residing there, and history of male-male sexual behavior. We estimate that it will take 5 minutes to complete the screener. We anticipate that 10% of those screened will be ineligible and 10%, after learning what participation in the project entails, will refuse to participate, yielding a total of 300 eligible respondents over a 12-month period. We estimate that it will take 40 minutes for each respondent to complete the behavioral assessment.

307.

308. RDS will occur at all 3 sites. At each site, approximately 330 individuals (990, total) will present themselves at a field location for eligibility screening. We estimate that it will take five minutes to complete the screener. We anticipate that 9% of respondents will be either not interested in completing the behavioral assessment or will be ineligible after completing the screener, yielding 300 eligible respondents per site (900, total). We estimate that it will take 40 minutes for each respondent to complete the behavioral assessment.

309.

310. For RDS, we anticipate that 40% of respondents will either not be eligible to recruit other participants or will not return to the interview site, and therefore will not answer the recruitment debriefing instrument. Therefore, we estimate that 180 respondents per site (540, total) will complete the recruitment debriefing instrument, which will take 2 minutes per respondent. These estimates cover the time that each respondent will spend communicating with the project staff and answering questions.

311.

312. FBS will occur at 2 sites. We anticipate that approximately 5000 individuals per site (10,000 total) will click on the Facebook ad. Of those who click on the Facebook ad, approximately 8% (410 per site, 820, total) will complete the landing page form, and of these, approximately 85% (350 per site; 700, total)

will present themselves at a field location for eligibility screening. We anticipate that approximately 14% of these individuals will be either ineligible or not interested in completing the behavioral assessment after completing the screener, yielding approximately 300 eligible respondents per site (600, total). We estimate that clicking on the Facebook ad, reading and completing the information on the landing page, and scheduling a time to come to the field site will take approximately 15 minutes per respondent. As with the other sampling methods, we estimate each respondent will take 5 minutes to complete the screener and 40 minutes to complete the NHBS-YMSM behavioral assessment.

313.

314. Because HIV testing is a clinical procedure, it is not included in the burden estimates.

315.316. Exhibit A.12.A Estimate of Annualized Burden Hours

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		mber	mber	ve	ota
		of	of	ra	l
		321. Re	324. Re	ge	Res
		spond	spons	Mi	pon
317. Type of	318. Form	ents	es per	nu	se
Respondent	Name		325. Re	te	331. B
Respondent	Name		spond	S	urd
			ent	328. P	en
				er Re	332. (
				sp	Hou
				on I	rs)
				se	
333. Key	334. Key	335 . 60	336. 1	337. 6	338. 6
Informants	informant			0/	Θ
	interview			60	
339. Focus Group	340. Focus	341 . 60	342. 1	343 . 6	344. 6
Participants	group			0/	Θ
	interview			60	
345. Young Men	346. Enumer	347. 10	348 . 1	349 . 2	350 . 4
Approached at	ation	0		/6	
Venues	interview			0	
351. Young Men	352. Eligib	353 . 37	354. 1	355 . 5	356 . 3
Screened – VBS	ility	6		/6	2
	screener			0	
357.	359.	361.	363.	365.	367.
358. Eligible	360. Behavi	362. 30	364. 1	366 . 4	368. 2
Young Men – VBS	oral	0		0/	00
	assessment			60	
369. Young Men	370. Eligib	371 . 99	372. 1	373. 5	374. 8
Screened – RDS	ility	0		/6	3
	screener			0	
375.	377.	379.	381.	383.	385.
376. Eligible	378. Behavi	380. 90	382. 1	384. 4	386. 6
Young Men – RDS	oral	0		0/	00
	assessment			60	
387.	389.	391.	393.	395.	397.
388. Peer	390. Recrui	392. 54	394. 1	396 . 2	398. 1
Recruiters	tment	0		/6	8
	debriefing			0	
399. Young Men	403. Landin	408 . 82	415 . 1	422. 1	429. 2
Recruited to	g page	0	416.	5/	05

317. Type of Respondent	318. Form Name	319. 320. Nu mber of 321. Re spond ents	322. 323. Nu mber of 324. Re spons es per 325. Re spond ent	326. 327. A ve ra ge Mi nu te s 328. P er Re sp on se	329. 330. T ota l Res pon se 331. B urd en 332. (Hou rs)
Field Site through Facebook Ads: 400. 401. Young Men Screened - FBS 402.	404. 405. 406. 407. Eligib ility screener	409. 410. 411. 412. 413. 414. 70	417. 418. 419. 420. 421. 1	60 423. 424. 425. 426. 427. 428. 5 /6 0	430. 431. 432. 433. 434. 435. 5
436. Eligible Young Men – FBS 442. Total	437. Behavi oral assessment 443.	438. 60 0 444.	439 . 1 445 .	440. 4 0/ 60 446.	441. 4 00 447. 1 715

449. A.12.B. Estimated Annualized Costs

450.

451. The annualized cost to respondents for the burden hours is estimated to be \$32,655; details are provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (http://www.bls.gov/news.release/pdf/ecec.pdf).

452. Exhibit A.12.B. Annualized Cost to Respondents

454. Act ivity	455. To tal Burden Hours	456. Hourly Wage Rate	457. Total Respondent Cost	
458. Key Informan t	459 . 60	460. \$19.04	461 . \$1,143	

Intervie W					
462. Foc us Group Intervie w	463 . 60	464.	\$19.04	465.	\$1,143
466. Enu meration Interview	467 . 4	468.	\$19.04	469.	\$76
470. Scr eened, Young MSM 471. (RD S, VBS, FBS)	472 . 168	473.	\$19.04	474.	\$3,199
475. Int erviewed , Young MSM (RDS, VBS, FBS)	476 . 1200	477.	\$19.04	478.	\$22,848
479. Deb riefed, Young MSM (RDS)	480 . 18	481.	\$19.04	482.	\$343
483. Recruite d to Field Site through Facebook Ads, Young MSM (FBS) 484.	485 . 205	486.	\$19.04	487.	\$3,903
488. Tot	489.	490.		491.	\$32,655
		I		I	

493.

494. <u>A.13.Estimates of Other Total Annual Cost Burden to Respondents</u> and Record Keepers

495.

496. There are no other costs to respondents or record keepers with this proposed collection of information. **497.**

499. A.14.Annualized Cost to the Federal Government 500.

The annualized cost of this project is estimated to be 501. \$1,972,350.

502.

503. Exhibit 14.A Estimated Cost to the Government

504.

<i>505</i> .		508.
506. E xpens e	507. Expense Explanation	509. Annual Costs (dollars)
Type 510 . D	511. NHBS-YMSM:	
	Personnel	
irect Costs		
to	512. Epidemiologist-13 1 90%	
the		
Feder	513 . \$80,000 514 . ORISE	
al	Fellow 1 100%	518. \$167,000
Gover	\$75,000	318. \$107,000
nment	515. Data	
Time II	Manager	
	1 50% \$40,000	
	516.	
	517.	
	520. Cooperative	
	agreement funds to	521. \$1,578,350
	project areas	41 , 575, 555
522. C	523. Contracted	
ontra	Questionnaire Programming	524. \$30,000
ctor	(2) 0.25 FTE	6241 \$66,666
and	526. Data Coordinating	
0ther	Center (CDC Contractor	527. \$188,300
Expen	for data collection)10%	4100,000
ses	529. Travel (6	
	trips*\$1,200)	530 . \$7,200
	532. Meetings and	
	Trainings	533 . \$1,000
	535. Printing	536. \$500
537.	538. TOTAL COST TO THE	·
337.	GOVERNMENT	539. \$1,972,350
F 40	00 1 E1(11)	

540.

The personnel hired specifically to conduct the NHBS-YMSM 541. data collection consists of 1 ORISE Fellow. Travel is related to providing technical assistance and conducting site visits. 542.

543. The information collection described in this request will be funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

544.

545.

546. <u>A.15.Explanation for Program Changes or Adjustments</u>

547.

548. Not applicable – request is for a sub-collection under a generic approval.

549.

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

551.

552. All data collection will be completed during the 12-month period after OMB approval. Data analysis will occur within 12 months of OMB approval. The following is a brief overview of the NHBS-YMSM Timeline.

553.

554. Exhibit 16.A Project Time Schedule

,55.				
556.		558.		
557 .	Activity	559.	Time Schedule	
560.	Preliminary	561.	Immediately after OMB	
res	research activities		roval	
562.	Interviewer	563.	1 month after OMB	
	ining	app	roval	
564.	Interviewing	565.	3-6 months after OMB	
par	participants		roval	
566.	Data management	567.	3-6 months after OMB	
		app	roval	
568.	Evaluation	569.	7-8 months after OMB	
		approval		
570.	Analysis	571.	9-12 months after OMB	
		approval		
572.	Publication	573.	12 months after OMB	
		approval		

574.

575.

576.

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

578.

579. The OMB Expiration Date will be displayed. No exception is requested.

580.

581. <u>A.18.Exceptions to Certification for Paperwork Reduction Act Submissions</u>

583. There are no exceptions to the certification.

584.

585.

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