applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than February 28, 2020.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Dry Lake Financial, LLC, Spur, Texas;* to become a bank holding company by acquiring up to 51 percent of the voting shares of Espuela Bankshares, Inc., and thereby indirectly acquire Spur Security Bank, both of Spur, Texas.

2. *Independent Bank Group, Inc., McKinney, Texas;* to merge with Texas Capital Bancshares, Inc., and thereby indirectly acquire Texas Capital Bank, National Association, both of Dallas, Texas.

Board of Governors of the Federal Reserve System, January 24, 2020.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2020–01565 Filed 1–28–20; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington, DC 20551–0001, not later than February 13, 2020.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Kim Marie Gundy, La Vista, Nebraska; Jill Ann Jacobsen, Forsyth, Illinois; Dean Xavier Langenfeld, Earling, Iowa; McKenzie Rae Bieker, Harlan, Iowa; Mark Albert Langenfeld II, Tipton, Iowa; Max Bernard Langenfeld, Earling, Iowa; and Magdalen Ann Langenfeld, Harlan, Iowa;* as a group acting in concert (Langenfeld Family Control Group) to join the Todd M. Langenfeld Revocable Living Trust Dated July 24, 1996, Todd M. Langenfeld, trustee, Earling, Iowa, and to retain voting shares of J. Carl. H. Bancorporation Inc., and thereby indirectly retain voting shares of Farmers Trust & Savings Bank, both of Earling, Iowa.

B. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *John E. Babcock, Anoka, Minnesota;* to retain voting shares of Metro North Bancshares, Inc. and thereby indirectly retain voting shares of The Bank of Elk River, both of Elk River, Minnesota. Additionally, the Anne Babcock Hollowed Trust, Anne Babcock Hollowed, trustee, both of Mercer Island, Washington, and the Beyer/Babcock Family Trust U/A DTD 4/6/00, Catherine Babcock, trustee, both of Altadena, California, to join as members of the Babcock Family Control Group to retain voting shares of Metro North Bancshares, Inc. and thereby indirectly retain voting shares of The Bank of Elk River.

Board of Governors of the Federal Reserve System, January 24, 2020.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2020–01566 Filed 1–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2313]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Oncology Indications in Direct-to-Consumer Television Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 28, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Study of Oncology Indications in Direct-to-Consumer Television Advertising. '' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Study of Oncology Indications in Direct-to-Consumer Television Advertising

(OMB Control Number 0910–NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes

FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of advertising features (content and format).

Oncology products are increasingly being promoted to consumers via direct-to-consumer (DTC) television advertising. Oncology indications are often complicated and supported by different clinical endpoints such as overall survival, overall response rate, and progression-free survival (Ref. 1) that are referenced in the DTC TV ads. The first objective of this project is to determine whether disclosing information about the nature of the endpoints that support the indications for oncology products helps consumers understand the drug's efficacy. This objective complements OPDP's research examining disclosing information about FDA's accelerated approval pathway to consumers (May 8, 2019, 84 FR 20148) and OPDP's research on disclosing oncology information to healthcare professionals (OMB control number 0910–0864—Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion). Although these studies all contribute to our knowledge of the communication of cancer treatment information, the current study specifically examines particular endpoints that are well-known to the professional oncology community and are now used in DTC advertising.

Because of the length of some indications, sponsors sometimes convey some of the indication in superimposed text rather than in the audio in the TV ads. The second objective is to test whether consumers adequately comprehend indication statements when portions of the indication are presented only in the superimposed text of television ads while other information is conveyed in the audio. This objective extends OPDP's previous research on the use of dual-modality *risk* presentations (presenting the information in two modes at the same time; OMB control numbers 0910–0634—Experimental Evaluation of the Impact of Distraction, 0910–0652—Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs, and 0910–0772—Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing) to the context of *indication* statements. This previous research supports the use of dual modality to increase consumers' understanding of risk information (January 27, 2012, 77 FR 4273) (Refs. 2 and 3).

We plan to conduct two rounds (one for each objective) of nine 1-hour in-person cognitive interviews of adults 18 years of age or older to refine the questionnaires and stimuli (18 participants total). We plan to conduct two pretests (one for each objective) not longer than 20 minutes, administered via internet panel, to test the experimental manipulations and pilot the main study procedures.

We plan to conduct two main studies (one for each objective) not longer than 20 minutes, administered via internet panel. For Study 1, we will create two television ads for fictitious oncology prescription drugs to increase the generalizability of the results (one solid tumor indication and one hematology indication). The ads will include audio claims about overall survival, overall response rate with and without a disclosure, or progression-free survival with and without a disclosure (see table 1 for the Study 1 design).

Some current television ads for oncology products include disclosures that are intended to help consumers differentiate surrogate endpoints like progression-free survival and overall response rate from overall survival. Examples include ''At the time of analysis, overall survival comparison was not yet available'' and ''Clinical trials are ongoing to determine if there is an overall survival benefit.'' The disclosure we use in the study will be based on disclosures currently in use and will be informed by consumer feedback elicited in focus groups conducted prior to the cognitive testing (approved under OMB control number 0910–0695). For example, the study disclosure may include language such as ''We currently do not know if Drug X helps people live longer.''

Participants will be randomly assigned to view one prescription drug television ad and then complete a questionnaire that assesses whether participants noticed the disclosure, their interpretations of the disclosure, their retention of the endpoint, and their perceptions of the drug's benefits and risks. We will also measure covariates such as demographics, cancer history, and literacy. Without a disclosure, we hypothesize that participants will not differentiate between overall survival, overall response rate, and progression-free survival. We hypothesize that a disclosure will help participants understand the surrogate endpoints (*i.e.,* overall response rate and progression-free survival) and thus will lead to greater understanding of the drug's efficacy compared with conditions without the disclosure. We will explore unintended effects of the disclosure, such as whether the disclosure lowers perceived efficacy compared with the overall survival condition.

For the second objective, in Study 2 we will vary the presentation of the products' indication, such that material information related to the indication will appear in superimposed text only, in the audio only, in both superimposed text and audio, or in neither (the control condition; see tables 2 and 3 for the Study 2 design). Participants will be randomly assigned to view a prescription drug television ad and then complete a questionnaire that assesses their retention and comprehension of the information. Following previous research on dual-modality presentations, we hypothesize that participants who view an ad with the material information in the audio and text will have greater retention of that information than participants in any other condition. We also hypothesize that participants who view an ad with the material information in the audio only will have greater retention of that information than participants in the superimposed text condition and the control condition. To test Study 1 and

2 hypotheses, we will conduct inferential statistical tests such as logistic regression and analysis of variance.

The questionnaires are available upon request from *DTCresearch@fda.hhs.gov*.

For all phases of this research, we will recruit a general population sample of adult volunteers 18 years of age or older. We will exclude individuals who work for the Department of Health and Human Services or work in the healthcare, marketing, or pharmaceutical industries. We will use literacy quotas to ensure that our sample includes participants with a range of literacy skills. We will also exclude pretest participants from the main studies, and participants will not be able to participate in both Studies 1 and 2. With the sample sizes described below, we will have sufficient power to detect small-sized effects in Studies 1 and 2 (table 4).

TABLE 1—STUDY 1 DESIGN

Indication	Overall survival	Overall response rate	Overall response rate with disclosure	Progression-free survival	Progression-free survival with disclosure
Solid Tumor					
Hematology					

Note: The solid tumor condition will be non-small cell lung cancer. The hematology condition will be multiple myeloma. Claims and disclosures are TBD, based on focus group feedback. Overall survival and progression-free survival claims will be the same for both indications. Study 1 will use the control ad from Study 2.

TABLE 2—STUDY 2 DESIGN: SOLID TUMOR

Material information in superimposed text only	Material information in audio only	Material information in superimposed text + audio	Material information not in superimposed text or audio (control)
Indication presentation			
Audio: Drug X is for adults with advanced non-small cell lung cancer. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene.	Audio: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer.	Audio: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene.	Audio: Drug X is for adults with advanced non-small cell lung cancer. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer.

Note: Study 2 will use the overall survival ad from Study 1.

TABLE 3—STUDY 2 DESIGN: HEMATOLOGY

Material information in superimposed text only	Material information in audio only	Material information in superimposed text + audio	Material information not in superimposed text or audio (control)
Indication presentation			
Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.

Note: Study 2 will use the overall survival ad from Study 1.

In the **Federal Register** of June 21, 2019 (84 FR 29213), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four submissions that were PRA-related. Within those submissions, FDA received multiple comments, which the Agency has addressed below.

(Comment 1) One comment voiced support for the current study and recommended future research to examine how DTC advertising addresses value-based care.

(Response 1) We thank the commenter for their support for this study and will consider their recommendations for future research.

(Comment 2) Two comments suggested limiting study recruitment to patients already diagnosed with and/or

treated for cancer and their caregivers and family members. The comments suggested that patients who have already been diagnosed and/or treated are likely to have a higher level of disease comprehension than the general population and that this would make the results more reflective of the population seeking cancer treatment information.

(Response 2) We chose a general population sample for the first study on this topic because of concerns about being able to recruit a sufficient number of participants if we selected a cancer-specific sample. However, we agree that in the future, a small, carefully-designed replication study with cancer patients and their caretakers and family members would be valuable. Prior to this study, we conducted both general-population focus groups and cancer-survivor focus groups. We will use the information gleaned from these focus groups to consider the ways in which these groups do and do not differ when discussing the limitations of the study's general-population sample. We will also ask participants if they have been diagnosed with cancer and whether they are a caregiver for someone with cancer.

(Comment 3) One comment suggested that the duration of the study ads be consistent with the duration of real-life ads.

(Response 3) The duration of the study ads will be consistent with the duration of real-life ads.

(Comment 4) One comment suggested adding screening questions to assess whether participants watch television, whether they watch ads, and how they are most likely to view DTC television ads.

(Response 4) We added questions about television viewing to the end of the questionnaire.

(Comment 5) One comment agreed with the hypothesis that consumers who view an ad with material information in both audio and text will have greater retention of that information. However, they do not believe there is enough time in a television ad to include the full indication in the audio, and they do not believe it is necessary because they believe the primary objective of ads is to raise product awareness so that consumers can seek additional information about the drug from health care providers or adequate provision sources.

(Response 5) The duration of the ads used in this study will be consistent with those currently airing on television and that duration will be sufficient to include all material information (Ref. 4) in the audio and text. While consumers may be able to find this information through other sources, the intent of this study is to determine what effect, if any, the material information has when delivered as an integrated part of the DTC advertisement.

(Comment 6) One comment notes that the Study 1 results would not be generalizable to an ad for a drug that has overall survival data but advertises with claims about overall response rate or progression-free survival.

(Response 6) We agree that our results would not generalize to this situation.

(Comment 7) One comment suggested wording changes for the claims in Study 1, including deleting ''decrease the number of detectable cancer cells in the body'' from the multiple myeloma overall response rate, describing progression-free survival as ''delayed disease progression or live longer without cancer getting worse,'' and using the disclosure statement ''clinical trials are still ongoing to determine if there is an overall survival benefit with Drug X.''

(Response 7) We thank the commenter for these suggestions and will consider them, along with the feedback from our focus group participants, when we finalize the language for the main study.

(Comment 8) One comment suggested changes to the Study 1 questionnaire, including rewording Q2 to make it clearer, adding a ''don't know'' response to Q4, removing Q5 because it is speculative, and rewording Q7 from ''any side effects it may have'' to ''side effects described in the ad.''

(Response 8) We revised Q2 to ask what the drug can do for people, added a ''don't know'' response to Q4, and edited Q7 as suggested. Q5 will only be asked of participants who already report that the drug will help people live longer; its purpose is to gauge their perception of how much longer people will live. We plan to keep this item, but we will cognitively test and pretest it to determine whether it should be revised or deleted.

(Comment 9) One comment suggested changes to the Study 2 questionnaire, including changing Q2 to ask about what disease the drug treats rather than who it is for, so it is less similar to Q4, adding Q10 from the Study 1 questionnaire to measure behavioral intentions, and revising Q7–Q12 because they are too detailed and require the respondent to recall a lot of information from the ad.

(Response 9) We agree that Questions 2 and 4 are similar; they are both designed to elicit responses related to the material information, not just the disease the drug is indicated to treat. However, Question 4 will only be asked of participants who respond ''no'' to Question 3. We believe this will provide context for those participants, but we will ask whether this series of questions is too repetitive or confusing in cognitive interviews, and we will review participants' responses in a pretest. We will add Q10a and Q10b to the Study 2 questionnaire. Questions 7 through 12 are designed to measure participants' retention and understanding of the material information. We will cognitively test and pretest the items to determine whether they should be revised or deleted.

FDA estimates the burden of this collection of information as follows:

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interview screener	30	1	30	0.08 (5 minutes)	2.4
Cognitive Interviews	18	1	18	1 (60 minutes)	18
Pretests 1 and 2 screener	200	1	200	0.08 (5 minutes)	16
Pretests 1 and 2	120	1	120	0.33 (20 minutes)	39.6
Study 1 screener	1,167	1	1,167	0.08 (5 minutes)	93.36
Study 1	700	1	700	0.33 (20 minutes)	231
Study 2 screener	867	1	867	0.08 (5 minutes)	69.36
Study 2	520	1	520	0.33 (20 minutes)	171.6
Total					641.32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Kim, J., J. Gao, L. Amiri-Kordestani, et al., ''Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer.'' The Oncologist, 10.1634/theoncologist.2018–0761, 2019. Available from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693727/*.

2. Aikin, K.J., A.C. O'Donoghue, C.M. Squire, et al., ''An Empirical Examination of the FDAAA-Mandated Toll-Free Statement for Consumer Reporting of Side Effects in Direct-to-Consumer Television Advertisements.'' *Journal of Public Policy & Marketing,* 35(1):108–123, 2016.

3. Sullivan, H.W., V. Boudewyns, A.C. O'Donoghue, et al., ''Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study.'' *Journal of Public Policy & Marketing,* 36(2):236–245, 2017.

4. 21 U.S.C. 321(n).

Dated: January 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01555 Filed 1–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 28, 2020.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Health Evaluation of Pregnancy Prevention Program Replications for High Risk and Hard to Reach Youth.

Type of Collection: OMB No. 0990–NEW.

Abstract: The Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is requesting approval by OMB of a new information collection request. OASH seeks to collect information to understand whether previously proven adolescent pregnancy programs have similar effects on knowledge, attitudes, beliefs, intentions, and behaviors related to sexual activity and health among different youth in different locations, especially among understudied and hard-to-reach youth. We propose to collect both qualitative and quantitative information in a quasi-experimental design with a matched comparison group. Eight organizations implementing a broad range of previously proven-effective pregnancy prevention programs (including sexual health education, sexual risk avoidance, and youth development programs) will recruit hard to reach or high-risk youth. Youth will complete surveys at baseline, immediately following the intervention, and at three months follow-up, yielding quantitative data about youth knowledge, attitudes, beliefs, intentions, and behaviors related to sexual health. Surveys will last for about 50 minutes. Focus groups yielding qualitative data about youth perspectives about adolescent pregnancy prevention programs will occur after the interventions are complete and will last for approximately 90 minutes.

Need and Proposed Use of the Information: Rates of pregnancy among hard-to-reach, high-risk, vulnerable, or understudied youth are significantly higher than the general population. However, there have been few evaluations assessing whether programs that have been previously proven successful can be delivered successfully to these youth. Hence, this evaluation is intended to help fill the evidence gap about the efficacy and effectiveness of existing pregnancy prevention programs among high-risk, vulnerable, or understudied youth. To enhance the rigor of the evaluation, a matched comparison group will be identified from select implementing organizations and their communities. OASH plans to use the findings of this evaluation to inform guidance to HHS grantees and prospective grantees on approaches for replication of pregnancy prevention programs for hard-to-reach and underserved youth.

Likely respondents: Respondents will include youth aged 12–16 years old, and their parents/guardians. Respondents will also include youth in a matched comparison group (''comparison youth'').

Burden: Exhibit 1 summarizes the total annual burden hours estimated for this ICR. This hour-burden estimate includes time spent by program youth, comparison group youth, and parents/guardians of both groups to complete data collection for the ICR.

Respondents	Form name	Max number of respondents	Average burden per response (hours)	Total max burden (hours)
Youth Program Participants	Baseline survey and youth assent	1,216	1.00	1,216
	First follow-up survey	730	0.83	608
	3-month follow-up survey	438	0.83	365
	Focus group assent	474	0.25	119