

Supporting Statement
Part A: Justification
FERTILITY KNOWLEDGE SURVEY

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Submitted by

Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Population Affairs

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Supporting Statement Part A: Justification

Fertility Knowledge Survey

A. JUSTIFICATION

The U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA) is requesting Office of Management and Budget (OMB) approval to conduct a web survey (Fertility Knowledge Survey). The purpose of the survey is to gather information to (1) assess the scope and accuracy of knowledge about human (female and male) fertility among adolescents and young adults and (2) understand the associations between fertility knowledge and childbearing behaviors and intentions. For the purposes of this study, female fertility, male fertility, and fertility knowledge are defined as follows:

Female fertility is the ability of a woman to get pregnant. Female fertility also includes the ability to give birth to a child.

Male fertility is the ability of a man to get a woman pregnant.

Fertility knowledge is actionable information about fertility throughout the life course, and the ability to apply this knowledge to one's own circumstances and needs. Specifically, it includes knowledge of information about the menstrual cycle and awareness (being conscious) of its role in fertility; knowledge of when and how pregnancy occurs and of the likelihood of pregnancy from unprotected intercourse at different times during the cycle and at different life stages; knowledge of other factors (e.g., sexually transmitted diseases) that may affect fertility; and knowledge and awareness of male fertility and factors that may affect it. Fertility knowledge and awareness also can include information on how specific family planning methods work, how they affect fertility, and how to use them; and it can create the basis for communication about and correct use of family planning.

The *Fertility Knowledge Survey* is a new data collection. The data collected from this survey will be generalizable to English-speaking women and men in the United States who are aged 15 to 29 years and able to get pregnant or father a child.

1. Circumstances Making the Collection of Information Necessary

The Office of Population Affairs (OPA) is responsible for implementing the mandated provisions of the categorical family planning grant program, Title X of the Public Health Service Act, 42 U.S. Code 300 (**Attachment A**). OPA operates under the direction of the Deputy Assistant Secretary for Population Affairs (DASPA) and advises the HHS Secretary and the Assistant Secretary for Health on a wide range of reproductive health topics, including family planning, adolescent pregnancy, sterilization, and other population issues. Its mission¹ is to:

- Assist individuals in determining the number and spacing of their children through the provision of voluntary, confidential and low-cost education, counseling, and related comprehensive medical services to eligible clients;
- Assist in making comprehensive, voluntary family planning services available to all persons desiring such services;
- Assist in coordinating domestic population and family planning research with the present and future needs of family planning programs;
- Enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services;
- Develop and make readily available information, including educational materials, on family planning and population growth to all persons desiring such information;
- Evaluate and improve the effectiveness of family planning service programs and population research; and
- Assist in training staff to effectively carry out family planning services.

Age is the strongest risk factor for infertility. Fertility begins to decline around age 32 and drops sharply after age 35.² Women in the United States, however, are marrying³ and having children at later ages.^{4,5} Nevertheless, the number of children they desire has remained the same. This means that the average age at which women give birth to their first and subsequent children has increased, placing them at ages where they are at higher risk for infertility and involuntary childlessness. In addition to advancing age, other threats to fertility include health and lifestyle factors like smoking, alcohol use, caffeine, being either underweight or obese, or having a sexually transmitted disease (e.g., chlamydia or gonorrhea) that causes permanent damage to the genital tract and leads to infertility.^{6,7} Findings from recent surveys^{8,9} among non-probability samples of reproductive aged women in the U.S. reveal critical gaps in fertility knowledge. High percentages of women lack awareness of the major (age) or other threats to fertility or believe myths and misconceptions about fertility or the adverse effects of contraceptive methods on future fertility. The few studies done with male respondents in the U.S. and Canada reveal similarly low levels of fertility knowledge.^{10,11}

Under its duties specified in 42 U.S.C. 300, Section 1004 (Title X Research), of the Title X Public Health Service Act, OPA is authorized to award grants and contracts to support “research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population,” including data analysis and related research and evaluation on issues of interest to the family planning field, as well as research into specific topic areas related to service delivery improvement. Section 1004 provides the authorizing legislation that necessitates this new data collection.

2. Purpose and Use of Information Collection

Possessing accurate knowledge about human fertility is critical information that enables reproductive-aged women and men to make informed decisions and plans about reproduction and empowers them to seek appropriate and timely health services (e.g., information and counseling, family planning, related preventive healthcare, or infertility assessment) to achieve those plans. The data collected from this survey will be generalizable

to English-speaking women and men in the United States, who are aged 15 to 29 years and able to get pregnant or father a child. The *Fertility Knowledge Survey (Attachment B)* will address the following five research questions (RQs):

- **RQ1:** What do adolescents and young adults know and believe about fertility? How extensive and accurate are their knowledge and beliefs about fertility?
- **RQ2:** Is there an association between knowledge and beliefs about fertility and reproductive attitudes, reproductive life plans, and childbearing behavior? To what extent do adolescents and young adults think about their reproductive life plan?
- **RQ3:** How and when do adolescents and young adults obtain information about fertility? What sources, if any, do they prefer or trust?
- **RQ4:** What role do healthcare practitioners play in informing individuals about fertility and related issues (e.g., pregnancy planning, contraceptive use and method choice, probability of getting pregnant, and threats to fertility)?
- **RQ5:** How do estimates for childbearing behaviors (age at first sex, number of partners, contraception use, and plans for children) compare between survey respondents and national survey data, such as the National Survey for Family Growth (NSFG)?

While not exhaustive, below are some examples that show a range of purposes and uses for the proposed information collection:

- Review and incorporate survey findings into reproductive life planning, sexual risk assessment, and counseling for adolescents and young adults with a goal of closing knowledge gaps, countering myths, and correcting misinformation about fertility and fertility-related behaviors.
- Use information about sources and trusted sources of fertility information to inform educational and informational strategies.
- Use information about the extent to which individuals receive fertility-related information and services to (1) assess Title X service policies and provider training and technical support needs and (2) ensure that the fertility knowledge and counseling skills reflect the evidence and best practices.
- Use the information from the survey to guide the incorporation of fertility-related services in Title X program reviews and performance monitoring.
- Communicate survey findings to OPA, policy makers, and other stakeholders, using strategies appropriate for each audience.
- Support secondary analysis of the *Fertility Knowledge Survey* data and dissemination of findings in the peer-review literature, at scientific meetings, and through the Family Planning National Training Center.

3. Use of Improved Information Technology and Burden Reduction

This study will rely on a web survey to be self-administered at home on personal computers, tablets, or phones, using two research panels (KnowledgePanel® and YouthPulse Panel) maintained by Ipsos.¹² The Ipsos research panels offer a probability-based online panel of the U.S. population and have been used by various federal agencies with HHS to collect data. **Exhibit 1** presents an illustrative list of HHS studies using the Ipsos KnowledgePanel®.

Exhibit 1-Selected OMB-Approved HHS Studies Using the Ipsos KnowledgePanel®

| HHS Agency | Title | OMB # | OMB Approval Expiration Date |
|------------|---|-----------|------------------------------|
| FDA | Risk and Benefit Perception Scale Development | 0910-0784 | 5/31/2018 |
| CDC | Extended Evaluation of the National Tobacco Prevention and Control Public Education Campaign | 0920-1083 | 2/13/2018 |
| CDC | Evaluation of the National Tobacco Prevention and Control Public Education Campaign | 0920-0923 | 3/31/2017 |
| FDA | Communicating Composite Scores in Direct-to-Consumer (DTC) Prescription Drug Advertising | 0910-0743 | 7/31/2016 |
| FDA | Healthcare Professional Survey of Prescription Drug Promotion | 0910-0730 | 2/29/2016 |
| FDA | Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages | 0910-0747 | 9/30/2015 |
| FDA | Examination of Online Direct-to-Consumer Prescription Drug Promotion | 0910-0714 | 7/31/2015 |
| CDC | Colorectal Cancer Screening Survey | 0920-1023 | 6/30/2015 |
| HHS | Survey on Long-Term Care Awareness and Planning | 0990-0417 | 5/31/2017 |
| FDA | Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising | 0910-0707 | 4/30/2015 |
| FDA | Experimental Study of Patient Information Prototypes | 0910-0691 | 8/31/2014 |
| FDA | Medical Device Decision Analysis: A Risk-Tolerance Pilot Study | 0910-0722 | 8/31/2014 |
| FDA | Comparing Nutrition Knowledge, Attitude, and Behavior Among English Dominant Hispanics, Spanish Dominant Hispanics, and Other Consumers | 0910-0706 | 4/30/2014 |
| CDC | Measuring Preferences for Quality of Life for Child Maltreatment | 0920-0930 | 4/30/2014 |
| OASH/OPA | Evaluation of the Parents Speak Up National Campaign: Youth Survey | 0990-0325 | 8/31/2011 |
| OASH/OPA | Evaluation of the Parents Speak Up National Campaign: Youth Survey | 0990-0325 | 8/31/2011 |
| OASH/OPA | Evaluation of the National Abstinence Media Campaign | 0990-0311 | 4/30/2009 |
| CDC | Examining the Efficacy of the HIV Testing Social Marketing Campaign for African American Women | 0920-0752 | 8/31/2008 |

CDC= Centers for Disease Control & Prevention. FDA=Food and Drug Administration. OASH/OPA=Office of the Assistant Secretary for Health/Office of Population Affairs. HHS=Department of Health & Human Services.

A web survey has numerous methodological advantages, including increased accuracy in measurement of key variables of interest, and reduced burden on study participants. These advantages include, but are not limited to:

- **Cost savings** – A web survey offers significant cost savings over traditional telephone or in person surveys (due to lack of human interviewers and interviewer training).
- **Flexible and timely data collection** – Because Ipsos does not involve interviewers and all ensuing requirements for interviewer training and quality control, data collection can be done more quickly and easily.
- **Privacy and reduce risk of bias** – Increased privacy, as compared to telephone interviewing, reduces vulnerability to socially desirable responses, particularly on sensitive subjects such as sexual and health behaviors. Surveys are self-administered in a private setting and respondents do not speak to human interviewers as they would with telephone surveys.
- **Flexible, convenient, and efficient for respondents** – The Ipsos web surveys allows respondents to complete the survey at a time convenient for them, and permits a respondent to stop before they have completed the survey and return to complete the survey at a later date within the specified time period. Furthermore, programmed skips result in respondents only seeing questions relevant to them based on their responses to prior questions.
- **Ipsos provides panel members with Internet access and hardware, if needed** – Unlike web convenience panels (also known as “opt-in” panels) that include only individuals with Internet access who volunteer themselves for research, Ipsos constructs the research panels using random, probability-based recruitment that covers households with and without Internet access. Providing panel members with Internet access and hardware, as needed, eliminates differential participation. Ipsos also offers technical support if panel members have difficulty accessing the internet or a particular survey, or have problems with the equipment itself.

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

After assessing the available data sources, OPA has determined that primary data are needed to effectively assess fertility knowledge and related behaviors among teenagers and young adults in the U.S. Studies identified through a review of published and gray literature were limited in terms of target population, survey scope or content, small or convenience samples, inclusion/exclusion criteria, and timeliness. Most studies focused on females, none assessed fertility knowledge and related behaviors among teens aged 15 to 17; only a few were based on data from probability sample.

Guided by the research questions identified in Section A.2, five domains of inquiry were identified, and existing surveys conducted by the U.S. Government and academic and private institutions in the U.S., Canada, Europe, and Australia were identified and reviewed. Federal surveys reviewed included the National Survey of Family Growth (NSFG), the Behavioral Risk Factor Surveillance System (BRFSS), the Youth Risk Behavior Surveillance System (YRBS), and Pregnancy Risk Assessment Monitoring System (PRAMS). Questions from existing surveys that addressed any of the five domains were evaluated and abstracted. The five domains and topics under each one included the following:

- **Domain 1–Fertility knowledge, awareness, and attitudes:** Fertility knowledge (e.g., facts, infertility risk factors, infertility myths, menstruation, fertile period), sources and exposure to fertility information, knowledge of egg freezing as a fertility preservation option, and self-perceived fertility;
- **Domain 2–Pregnancy/childbearing attitudes, and behaviors:** Pregnancy/childbearing history, reproductive/fertility intentions, attitudes about pregnancy/childbearing, intentions regarding fertility preservation in the event of a delay in childbearing, sexual activity/behaviors, contraceptive use, and knowledge/myths about contraception;
- **Domain 3–Access to fertility and other reproductive health information/care:** Healthcare access and use, discussion of fertility topics with healthcare provider, and sources of information on reproductive health;
- **Domain 4: Health and risk behaviors associated with fertility knowledge, awareness, and attitudes:** Self-perceived health status, health behaviors [e.g., smoking, weight, sexually transmitted diseases (STD)], and sexual risk behaviors (e.g., multiple sexual partners); and
- **Domain 5: Socio-demographic characteristics:** Demographic characteristics, socioeconomic characteristics, other associated factors (e.g., religiosity, sexual orientation).

To the extent possible and where appropriate, questions from existing federal surveys were used or adapted (e.g., modified wording or collapsing response categories) to construct the *Fertility Knowledge Survey*. For questions on sociodemographic characteristics, priority was given to federal surveys that included adolescent-aged respondents. The NSFG (female and male) was a key source for questions related to pregnancy, childbearing, contraceptive use, and receipt of fertility or other sexual and reproductive healthcare. The *Fertility Knowledge Survey* has incorporated selected NSFG questions about childbearing, sexual activity and contraception, and infertility care. The overlap, however, is minimal. The NSFG collects detailed information on a broad range of reproduction-related topics. The *Fertility Knowledge Survey*, in contrast, is narrowly focused on fertility knowledge, childbearing intentions and plans, and other fertility-related factors.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public. This collection will not involve small business or small entities.

6. Consequences of Not Collecting the Information or Less Frequent Collection

The *Fertility Knowledge Survey* will be administered once to each respondent. If the survey is not implemented, OPA will lack high-quality data and information needed to develop (a) a comprehensive understanding of the scope and accuracy of fertility knowledge among U.S. adolescents and young adults or (b) to design, test, and implement educational and other strategies aimed at increasing fertility knowledge and reducing adverse reproductive outcomes.

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

The proposed data collection is consistent with guidelines set forth in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Comments in Response to the Federal Register Notice. A 60-day Federal Register Notice, published on in the *Federal Register* on October 3, 2018 [Vol. 83, No. 192, pp. 49936-37] solicited public comment (**Attachment C**). No public comments were received.

Consultation with Subject Matter Experts. In developing the survey instrument, OPA consulted with three external fertility experts and substantive experts at RTI International. Consultation with the three external fertility knowledge experts consisted of review of several drafts of the *Fertility Knowledge Survey* questionnaire, participation in two 2-hour conference calls, and individual consultation on selected questions. In **Exhibit 2**, for each identifiable non-OPA stakeholder we present the following: year of consultation; name, title, and affiliation; and phone and email contact information.

Exhibit 2–List of Individuals that Provided Extensive Review and Feedback on the Fertility Knowledge Survey

| Year | Name/Title/Affiliation | Phone/Email |
|------|--|--|
| 2018 | Rebecka Lundgren, PhD, MPH Deputy Director and Research Director Institute for Reproductive Health Georgetown University | (202) 687-7969 lundgrer@georgetown.edu |
| 2018 | Judith Daniluk, PhD, Professor University of British Columbia | (604) 822-5768 judith.daniluk@ubc.ca |
| 2018 | Rashmi Kudesia, MD, MSc, FACOG Fertility Physician Houston IVF | (248) 225-4127 rashmi.kudesia@gmail.com |
| 2018 | Christina Fowler, PhD, Project Director RTI International | (919) 316-3447 cfowler@rti.org |
| 2018 | Helen P. Koo, PhD, Senior Advisor RTI International | (919) 493-1207 hpk.contractor@rti.org |

Cognitive and usability testing of online survey. RTI conducted cognitive and usability testing of the full, online survey instrument with nine women and men (aged 16 to 29 years). No personally identifiable information was collected from the testing participants. The purpose of cognitive and usability testing was to assess how well and with what ease the testing participants were able to complete the survey. Specific research questions for the cognitive and usability testing were as follows:

- Do testing participants understand the questions and are they able to respond as intended? Are there specific questions that are difficult to answer? Are the response options adequate? Are there any differences by age group or sex?

- Do participants understand key terms (e.g., fertility, infertility, to father) that are essential to understanding the instructions, introductions, questions, and response options? If not, which terms require clarification?
- Do participants understand other general terms (e.g., long-term, unprotected, regular) in a consistent way? If not, which terms require clarification?
- Do test participants perceive the survey's online visual layout, design, and navigational features to be user friendly?

Cognitive and usability testing consisted of 75-minute in-person, one-one-one interviews during which a trained interviewer used the concurrent think-aloud method of cognitive testing to solicit participants' feedback through question-specific and retrospective probes. During the interview, the participant completed the survey online. The interviewer was able to view the screen of the laptop used by the participant via a separate monitor connected to the participant's laptop. With permission of the participants, eight of the nine interviewers were audiotaped and observed by another member of the research team. Interviewers and participants were matched by sex, and participants received a \$75 payment for their time.

During testing, most participants understood the questions, key terms, and phrases and were able to provide appropriate responses. Some technical terms were unfamiliar to some participants, and other terms and phrases were not defined and were interpreted inconsistently. For most questions, participants found the response options appropriate and suitable. Some participants noted that some questions were more sensitive, but they did not have difficulty answering them. Participants did not experience usability or navigation challenges.

In response to participant feedback and in consultation with RTI survey methodologists, the team made the following changes to the survey: defining or describing key terms and phrases on every page where they appear; using the definitions of "female fertility" and "male fertility" instead of the terms themselves; placing descriptive text before versus after the survey question; defining vague terms and phrases; revising the instructions for true/false statements; and bolding or underlining words for emphasis.

9. Explanation of Any Payment/Gift to Respondents

There are two types of incentives for survey: a general incentive, which is independent of the survey, and an incentive that is specific to the survey. These incentives are described

below and summarized in **General incentives**. Ipsos provides general incentives to KnowledgePanel® members to maintain a high degree of panel loyalty and to prevent panel attrition. These incentives occur for any survey that is completed by a KnowledgePanel® or YouthPulse panelists and are not specific to their participation in the Fertility Knowledge Survey. For panel members lacking an Internet device, Internet service, or both, Ipsos provides as an incentive one or both, as needed. For KnowledgePanel® members using their own personal computers and Internet service, Ipsos enrolls the panelists in a points program that is analogous to a “frequent flyer” card. KnowledgePanel® members are credited with points in proportion to their regular participation in surveys; they receive cash-equivalent checks approximately every 4 to 6 months in amounts reflecting their panel participation level, commonly \$2 to \$6 per month. Once they accrue 25,000 points, Ipsos sends them a check for \$25. As a loyalty incentive, KnowledgePanel® members who complete a survey of 16 minutes or longer are entered into a sweepstakes. ¹ Per the participation terms of YouthPulse Panel, panel members will receive \$10 per completed survey and no additional incentives. YouthPulse Panel members receive their payment in check form..

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Exhibit 3–General and Study-Specific Incentives by Ipsos Research Panel

| Panel | General Incentive(s) | Study-Specific Incentive |
|---|--|----------------------------------|
| KnowledgePanel® Member who does not own a personal device or have internet | --Equipment (e.g., laptop) --Internet access | \$5 (equivalent in points=5,000) |
| KnowledgePanel® Member who owns a personal device and has internet access | --1,000 points --Sweepstakes incentive ^a (survey ≥ 16 minutes) | \$5 (equivalent in points=5,000) |

^a The Sweepstakes is a loyalty incentive, which is automatically added for any survey with an estimated completion time of 16 minutes or longer (including any screener questions). PRIZES: One (1) Grand Prize:

| | | |
|------------------|------|-----|
| YouthPulse Panel | \$10 | \$0 |
|------------------|------|-----|

Incentives specific to this data collection. In addition to the general incentives described above, KnowledgePanel® members will also receive 5,000 points (\$5 equivalent) for completing the *Fertility Knowledge Survey*. A \$5 (equivalent) is a standard incentive amount for longer surveys and surveys fielded with groups that have higher nonresponse. Internal Ipsos research has demonstrated that monetary incentives increase the survey completion rate by approximately five percentage points; the increase is larger for such groups as young adults and Hispanics. The payment of an additional incentive is intended to increase survey completion, especially among subgroups (teenagers 15 to 19 years or males 25 to 29 years) with historically lower response. The *Fertility Knowledge Survey* is longer (about 20 minutes) than many surveys administered to the panels, and the survey topics (fertility and childbearing) are more personal and may be sensitive for some respondents. YouthPulse panelists will receive no additional incentive beyond the general incentive described above.

10. Assurances of Privacy and Confidentiality Provided to Respondents

Administration of the *Fertility Knowledge Survey* qualifies as humans subjects research as defined in the Federal Policy for the Protection of Human Subjects Research (45 CFR 46). The study has been approved by Institutional Review Boards at RTI and MITRE (**Attachment D**). Furthermore, the study has also received a Certificate of Confidentiality (CoC) (**Attachment E**).

Privacy. Ipsos will keep the data private to the extent allowed by law. The *Fertility Knowledge Survey* will collect no personally identifiable information (PII). During recruitment of the research panels (i.e., unrelated to this study), Ipsos collects individual respondent’s PII (e.g., name, address, email address, and the names and ages of household members) solely for purposes of conducting its research business, which include pre-qualifying members or households for surveys, communicating with panel members, and ensuring a nationally representative panel. Once recruited to participate in the panel, Ipsos uses periodic surveys to collect a range of demographic, social, health, attitudinal, and other information about panel members and their households. PII collected by Ipsos for conducting its research business is maintained in a separate database from completed questionnaires and computerized data files used for analysis. The survey response data are identified only by an incremented ID number. Ipsos will provide the data analysis contractor (RTI International) and funding agency (OPA) a data file with no PII (de-identified). The following attachments present Ipsos’s privacy-related assurances to panel members and other statements: *The KnowledgePanel® Bill of Rights and” The Deal”* (**Attachment L**), *Privacy Statement for KnowledgePanel® Members* (**Attachment M**), *Ipsos Commitment to Privacy and Data Protection* (**Attachment N**).

With regard to assurances of privacy provided to survey respondents, the adult survey invitation and consent form (**Attachments F and H**), parent invitation/permission form

\$2,000 Visa Prepaid Card (ARV \$2,000); One (1) First Prize –one (1) \$1,000 Visa Prepaid Card (ARV \$1,000); One (1) Second Prize – one (1) \$500 Visa Prepaid Card (ARV \$500); One (1) Third Prize – (1) \$250 Visa Prepaid Card (ARV \$250); Ten (10) Fourth Prizes – one (1) \$50 Visa Prepaid Card (ARV \$50); Actual Reward Value (“ARV”) is based on the MSRP (manufacturer’s suggested retail price) of each prize.

(**Attachments G and I**), and minor assent form (**Attachment J**), provide panelists with the following assurances:

- The survey will not collect any information (such as name, address, or email address) that could link the respondent to his or her answers.
- Ipsos will not share with the study researchers or the study sponsor any PII (name, address, email address) that the respondent has already shared as part of their membership in the panel and that could link them to their answers. Respondents are also assured that no one will try to sell them anything.
- Ipsos will provide RTI with a fully de-identified dataset (i.e., no PII or IP addresses) at the completion of data collection, and the respondent will never be identified individually in any analysis, report, or publication.
- Investigators have obtained a CoC and the extent to which the CoC protects participant privacy. The specific CoC-related statement is as follows:

“A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers may not disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or program evaluation by the agency (Office of Population Affairs) funding this study. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.”

Confidentiality. Ipsos uses industry-standard security technology, procedures, and other measures to protect data collection (secure website) and storage. Ipsos has developed a secure transmission and collection protocol including the use of system passwords, and two separate sets of firewalls to prevent unauthorized access to the system. When Ipsos assigns a survey to a panel member, the panelist receives a notice in their password-protected email account that a survey is available for completion. Respondents can also access their assigned surveys from their password protected individual landing page on the panel website. Neither completed questionnaires nor individual survey responses are stored onto the Ipsos-provided laptops; questionnaires are administered dynamically over the Internet. Survey responses are written in real-time directly to Ipsos’s server and are then stored in a local Oracle database. The database is protected primarily through firewall restrictions, password protection, and 128-bit encryption technology. In transmitting the final data to RTI, Ipsos will encrypt the data file for transmission. Upon receipt, RTI staff will save the file to the project share on server that is backed up nightly and to which only authorized staff have access. The *Ipsos Commitment to Privacy and Data Protection* is found in **Attachment N**.

With regard to assurances of confidentiality provided to survey respondents, all consent, permission, and assent forms (**Attachments H, I, and J**), and the FAQ included in the invitations (**Attachments F and G**), provide respondents a confidentiality assurance that reads as follows:

“Ipsos has processes in place to keep answers surveys confidential. You can answer the survey questions on a computer, laptop, tablet, or smartphone. Although the guarantee of confidentiality of data transmitted on the Internet cannot be absolute, your answers will be transmitted and saved in a secure way to prevent viewing by anyone who does not have permission to do so, and to prevent loss, alteration, or misuse of your answers.”

11. Justification for Sensitive Questions

While a primary focus of the *Fertility Knowledge Survey* is to collect data to assess respondents’ knowledge of human fertility, it includes questions on other fertility-related topics (e.g., sex, pregnancy, birth control, sexually transmitted diseases, weight, smoking, and alcohol use) that may be sensitive for some people. The inclusion of questions on these potentially sensitive topics is justified to (a) allow examination of the associations between levels of fertility knowledge and important and modifiable reproductive attitudes and behaviors, and (b) increase the practical utility of findings in guiding policy improvements and interventions that increase fertility knowledge and counter misinformation. The NSFG, which asks extensive and detailed information on some of the topics covered by the *Fertility Knowledge Survey*, has reported no problems with asking questions on these potentially sensitive topics because, according to the most recent NSFG Supporting Statement,¹³ family formation, sexual activity, and childbearing are “important and positive aspects” of the lives of reproductive aged individuals.

Nevertheless, steps will be taken to minimize the sensitivity and increase the awareness among respondents of the importance of the data collection efforts on these potentially sensitive topics. These steps include:

- Invitation letters and consent, permission, and assent forms [**Attachments F to J**] describe the topics addressed in the survey and state that the data collection is sponsored by the U.S. Department of Health and Human Services and that the data collected will be put to important uses.
- The web survey will be self-administered, which allows the respondent to have maximum control over the privacy of the setting in which the survey is completed and reduces any embarrassment or bias (e.g., social desirability) that might be introduced with an in-person interview.
- The survey structure—order of questions, question wording, assurances of privacy and confidentiality of responses, and overall and section introductory text—is designed to put respondents at ease and to make them aware of upcoming potentially sensitive questions. Where respondents may lack certainty about how to answer a question, they may be assured that “A best guess is fine” or be offered “Don’t know” or “Not sure” response options.

- Finally, the survey introduction and consent, permission, and assent forms state that the survey is voluntary, that respondents may skip questions that make them embarrassed or uncomfortable, and that respondents may discontinue the survey without penalty (e.g., discontinuation will not affect panelists' ability to participate in future surveys).

12. Estimates of Annualized Burden Hours (Total Hours and Wages)

12A. Estimated Annualized Burden Hours

The estimated annualized hour burden of responding to this information collection is **1,333 hours**, or a weighted average of **20 minutes (.33 hours)** per respondent (*Exhibit 4*). The hour-burden estimate includes the time spent by a respondent to read the email invitation, review the online consent or assent (minor), and complete the survey.

Exhibit 4–Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Annualized Burden per Response (Hours) | Annualized Total Burden (Hours) |
|--------------------|----------------------------|-----------------------|------------------------------------|--|---------------------------------|
| Individual | Fertility Knowledge Survey | 4,000 | 1 | 20/60 | 1,333 |

This weighted average hour burden accounts for differences in the electronic technology (e.g., mobile phone, computer/laptop, or tablet) that respondents may use to complete the survey. A survey completed on a mobile phone may take 30% to 60% longer. Younger respondents are more likely than older ones to use a mobile phone to complete the survey. For purposes of estimating overall hour burden, Ipsos has assumed that 50% will use a portable device. Furthermore, the number of questions that a respondent will answer will vary based on sex, number of children, marital or relationship status, plans for having future children, sexual experience and activity, health insurance status, and lifestyle factors (smoke or drink). The online survey will be programmed to display only questions that are relevant to the respondent based on responses to prior questions.

12.B. Estimated Annualized Respondent Cost Burden

The estimated total annualized labor cost to complete the *Fertility Knowledge Survey* is **\$21,160**, or an average of **\$5.29** per respondent (see). The hourly wage is based on current published estimates of the usual weekly earnings of wage and salary workers (Second Quarter 2018) reported by the Bureau of Labor Statistics. The estimated hourly wage rates are based on median weekly earnings for females and males aged 16-24 years and 25 years or older and the assumption of a 40-hour work week.¹⁴ These costs have not been adjusted for fringe benefits and overhead because direct wage costs represent the “opportunity cost” to respondents for time spent on survey completion.

Exhibit 5–Estimated Annualized Cost to Respondents for Information Collection

| Type of Respondents | Number of Respondents | Total Hour Burden | Hourly Wage Rate | Respondent Cost |
|---------------------|-----------------------|-------------------|------------------|-----------------|
| Female | | | | |
| 15 to 24 years | 1,400 | 467 | \$12.78 | \$5,964 |
| 25 to 29 years | 700 | 233 | \$20.60 | \$4,806* |
| Male | | | | |
| 15 to 24 years | 1,400 | 467 | \$13.20 | \$6,160 |
| 25 to 29 years | 500 | 167 | \$25.38 | \$4,230 |
| Total | 4,000 | | | \$21,160 |

*Rounded down to accommodate rounding error

13. Estimated Annualized Respondent Nonlabor Cost Burden

There will be no capital, operating, or maintenance costs to the respondents.

14. Annualized Cost to Federal Government

The annualized cost for developing, testing, and administering the Fertility Knowledge Survey questionnaire; analyzing the data, and planning for dissemination of findings is \$561,000, totaling \$1,122,000 (Exhibit 6) for the two-year period of the MITRE contract (with subcontractors RTI and Ipsos).

Exhibit 6-Annualized Cost of Fertility Knowledge Data Collection to Federal Government

| Source | Amount (\$) |
|--|-------------|
| MITRE Contract for survey development and implementation | \$561,000 |

15. Explanation for Program Changes or Adjustments

This is a new, one-time information collection request. Therefore, all the burden is considered to be new burden and will be accounted for as a “program change due to agency discretion” for the purposes of OMB’s PRA inventory. The burden will be removed from OMB PRA inventory after the survey is completed.

16. Plans for Tabulation and Publication and Project Time Schedule

The timetable in **Exhibit 7** assumes OMB approval on or around April 18, 2019, and completion of data collection, analysis, and dissemination activities by September 11, 2019.

Exhibit 7-Timetable for Data Collection, Analysis, and Publication

| Activity | Expected Date of Completion |
|---|-----------------------------------|
| Incorporate final, OMB approved edits to the online survey | Within 1 month after OMB approval |
| Pretest final instrument with a maximum of 9 individuals | Within 1 month after OMB approval |
| Field online survey | 2-3 months after OMB approval |
| Complete survey | 3 months after OMB approval |
| Prepare de-identified and weighted dataset and documentation | 3 months after OMB approval |
| Perform and submit report with a descriptive analysis of the data | 3-4 months after OMB approval |

| Activity | Expected Date of Completion |
|---|-----------------------------|
| Submit de-identified and weighted dataset and documentation | 4 months after OMB approval |
| Submit outlines for 5 manuscripts | 4 months after OMB approval |

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

The 3-year expiration date for OMB approval will be displayed on all versions of the survey instrument (i.e., electronic, and hard copy).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

- 1 Office of Population Affairs. (2016). Mission. Accessed from <https://www.hhs.gov/opa/about-opa/mission/index.html>
- 2 The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and The Practice Committee of the American Society for Reproductive Medicine. ACOG. (2014) Female age-related fertility decline. *Fertility and Sterility*, 101(3):633-634.
- 3 U.S. Census Bureau. (2017). Historical Marital Status Tables. Accessed from <https://www.census.gov/data/tables/time-series/demo/families/marital.html>
- 4 Daugherty, J and Martinez, G. (2016). Birth Expectations of U.S. Women Aged 15-44. NCHS Data Brief, NO. 260, October 2016. Accessed from <https://www.cdc.gov/nchs/data/databriefs/db260.pdf>
- 5 Mathews, TJ and Hamilton, BE. (2016). Mean Age of Mothers is on the Rise: United States, 2000-2014. NCHS Data Brief, No. 232, January 2016. Accessed from <https://www.cdc.gov/nchs/data/databriefs/db232.pdf>
- 6 Practice Committee of the American Society for Reproductive Medicine and the Society for Reproductive Endocrinology and Infertility. (2017). Optimizing natural fertility: a committee opinion. *Fertility and Sterility*, 107(1):52-58.
- 7 Centers for Disease Control and Prevention. (2017). STDs & Infertility. Accessed from <https://www.cdc.gov/std/infertility/default.htm>
- 8 EMD Serono. (2011). *In the Know: Fertility IQ 2011 Survey*. Accessed from https://www.npr.org/assets/news/2011/11/FertilityWhitePaper_Final.pdf
- 9 Lundsberg, L.S., et al. (2014). Knowledge, attitudes, and practices regarding conception and fertility: a population-based survey among reproductive-age women. *Fertility and Sterility*, 101(3):767-774.
- 10 Daumler, D, et. al. (2016). Men's knowledge of their own fertility: a population-based survey examining the awareness of factors that are associated with male infertility. *Human Reproduction*, 31(12): 2781-2790. Peterson, B.D., et al. (2012). Fertility awareness and parenting attitudes among American male and female undergraduate university students. *Human Reproduction*, 27(5): 1375-1382.
- 11 Daniluk, JC and Koert, E. (2013). The other side of the fertility coin: A comparison of childless men's and women's knowledge of fertility and assisted reproductive technology. *Fertility and Sterility*, 99(3):839-846.
- 12 Ipsos website: <https://www.ipsos.com/en-us>
- 13 National Center for Health Statistics. (June 4, 2018). *Supporting Statement A Revision Request for Clearance: National Survey of Family Growth*. Accessed from https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201804-0920-011
- 14 Bureau of Labor Statistics. Usual Weekly Earnings of Wage and Salary Workers. Second Quarter 2018. BLS Economic News Release July 17, 2018. Accessed from <https://www.bls.gov/news.release/pdf/wkyeng.pdf>