# 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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# Contents

Α.	JUSTIFICATION	1
1.	Circumstances Making the Collection of Information Necessary	1
2.	Purpose and Use of Information Collection	2
3.	Use of Improved Information Technology and Burden Reduction	4
4.	Efforts to Identify Duplication and Use of Similar Information	6
5.	Impact on Small Businesses or Other Small Entities	7
6.	Consequences of Not Collecting the Information or Less Frequent Collection	7
7.	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	7
8.	Comments in Response to the Federal Register Notice/Outside Consultation	7
9.	Explanation of Any Payment/Gift to Respondents	8
10.	Assurances of Privacy and Confidentiality Provided to Respondents	9
11.	Justification for Sensitive Questions1	1
12.	Estimates of Annualized Burden Hours (Total Hours and Wages)1	2
13.	Estimated Annualized Respondent Nonlabor Cost Burden1	3
14.	Annualized Cost to Federal Government1	3
15.	Explanation for Program Changes or Adjustments1	3
16.	Plans for Tabulation and Publication and Project Time Schedule1	4
17.	Reason(s) Display of OMB Expiration Date Is Inappropriate1	5
18.	Exceptions to Certification for Paperwork Reduction Act Submissions1	5

#### **EXHIBITS**

Exhibit 1-List of Individuals that Provided Extensive Review and Feedback on the Fe	rtility
Knowledge Survey	8
Exhibit 2-General and Study-Specific Incentives by Ipsos Research Panel	9
Exhibit 3-Estimated Annualized Burden Hours	12
Exhibit 4-Estimated Annualized Cost to Respondents for Information Collection	13
Exhibit 5–Annualized Cost of Fertility Knowledge Data Collection	
to Federal Government	13
Exhibit 6-Timetable for Data Collection, Analysis, and Publication	14

# ATTACHMENTS

Α.	Authorizing LegislationA - 1
Β.	Fertility Knowledge Survey: Female & Male VersionsB – 1
C.	Federal Register NoticesC - 1
D.	Notice of RTI Institutional Review Board Study ApprovalD - 1
E.	Email InvitationE - 1
F.	Consent FormF - 1
G.	Email RemindersG - 1
Н.	The Deal: Your Rights and Responsibilities as a KnowledgePanel® MemberH - 1
I.	Privacy Policy for KnowledgePanel <sup>®</sup> MembersI - 1
J.	Statement of Ipsos's Commitment to Privacy and Data ProtectionJ - 1
К.	Certificate of ConfidentialityK - 1

#### 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 *Fertility Knowledge Survey* is a new data collection.

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.

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.<sup>1</sup>

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

**Need.** 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.

Age is the strongest risk factor for women's infertility. Women's fertility begins to decline around age 32 and drops sharply after age 35.<sup>2</sup> Women in the United States, however, are marrying<sup>3</sup> and having children at later ages.<sup>4,5</sup> Nevertheless, the number of children they desire has remained almost the same.<sup>4</sup> This means that the average age at which women give birth to their first and subsequent children has increased, placing some women at ages where they are at higher risk for infertility and involuntary childlessness.<sup>6</sup> 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.<sup>7,8</sup>

Findings from a small number of surveys,<sup>9,10</sup> nearly all among convenience (e.g., university students) or other non-probability samples of reproductive aged women in the U.S., reveal gaps in fertility knowledge. Some women lack awareness of the major (age) or other determinants of 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 gaps in fertility knowledge.<sup>11,12</sup> We identified only one study<sup>13</sup> that used data (*2009 Survey of Young Adults* or "*Fog Zone*") that used a national probability-based sample of unmarried women and men (18–29 years of age) to examine perceived infertility as a risk factor for contraceptive nonuse and unplanned pregnancy. The *Fog Zone* survey focused on unplanned pregnancy risk factors; it did not inquire about infertility risk factors (e.g., age).

The *Fertility Knowledge Survey* will explore an array of fertility knowledge items, infertility risk factors, and fertility-related attitudes and behaviors in a large convenience sample of young adults. To our knowledge, it will be the largest such survey that includes women and men and asks each sex the same (or similar) questions as the other sex, to assess their knowledge of both female and male fertility. The survey will include women and men 18–29 years of age who are in or entering their reproductive years, for whom infertility is less common and who are young enough to avoid infertility related to age or other risk factors. The survey will not allow generalizability to the US population of young adults or to create national statistics. Rather, the study will allow exploration of the knowledge in this cohort, thereby allowing us to determine the need for educational programs and their content. It will also allow us to generate hypotheses that could be explored in future research.

**Statutory Basis.** OPA's mission<sup>14</sup> is to promote health across the reproductive lifespan through innovative, evidence-based adolescent health and family planning programs, services, strategic partnerships, evaluation, and research. OPA operates under the direction of the Deputy Assistant Secretary for Population Affairs (DASPA) who also serves as the Director of the Office of Adolescent Health. OPA 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. OPA administers the Title X family planning program, the Teen Pregnancy Prevention program, the Pregnancy Assistance Fund, and the embryo adoption program.

Under its duties specified under 42 U.S.C. 300, Section 1004 (*Attachment A*), OPA is authorized 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 and service delivery improvement. OPA's support for the *Fertility Knowledge Survey* is consistent with the agency's statutory authority.

# 2. <u>Purpose and Use of Information Collection</u>

**Purpose.** The purpose of the *Fertility Knowledge Survey* (*Attachment B*) is to gather information that allows HHS to explore knowledge about the childbearing preferences and plans, attitudes and behaviors, and knowledge of fertility among young men and women.

From this information, HHS will determine the need for educational programs and their content, as well as the need for future research.

The survey will be administered via the internet to a non-probability sample of Englishspeaking women and men in the United States (U.S.) who are aged 18–29 years and able to get pregnant or father a child. The internet panels (KnowledgePanel<sup>®</sup> and YouthPulse Panel) are maintained by Ipsos. Because this is a non-probability sample, the survey data will not be used to generate generalizable statistics for young men and women.

Considering limitations of funding, time constraints, and goals of the data collection, a nonprobability sample using an internet panel will be suitable. OPA intends for this study to provide *exploratory descriptive information* on young adults' fertility knowledge and relevant fertility-related attitudes and behaviors, and allow for *analyses* to explore potential demographic characteristics associated with fertility knowledge and thus individuals with these characteristics who could benefit from increased availability of fertility-related education, information, counseling, and services.

To meet OPA's informational needs, the following research questions (RQ) were developed to guide questionnaire development and analysis:

- **RQ1**: What do individuals in the study sample know about female and male fertility? Are there individuals with certain demographic characteristics (e.g., men aged 18-24) in the study sample that are associated with lower levels of knowledge and thus who could benefit from improved or increased fertility-related education, information, counseling, and services? Do these relationships suggest future research needs?
- **RQ2:** What is the relationship between fertility knowledge and plans for or attitudes about having children in this cohort? For instance, do women planning to delay having children until they are in their 30s have lower levels of knowledge than those who plan to have children sooner? Can such relationships help us design educational programs or services? Do these relationships suggest future research needs?
- **RQ3:** What sources of information have individuals in the study sample used to obtain fertility-related information? Which sources do they trust most to provide them with correct information? Do those who obtain information from nonmedical sources like a friend or acquaintance have lower levels of fertility knowledge? Can such relationships help us design educational programs or services? Do these relationships suggest future research needs?
- **RQ4:** What is the level of fertility knowledge among individuals in the study sample who have received fertility-related information from a health provider? Do those who report receiving no or little information about fertility from a health provider have lower levels of knowledge? Can such relationships help us design educational programs or services? Do these relationships suggest future research needs?
- **RQ5:** Does the level of fertility knowledge among individuals in the study sample vary by access to health care. For instance, acknowledging that people with more limited access to health may not be well represented in the sample, do those without a regular source

of care or those who have not visited a health provider in the past 12 months have lower levels of knowledge? Can such relationships help us design educational programs or services? Do these relationships suggest future research needs?

• **RQ6:** Are there relationships between the fertility knowledge of individuals in the study sample who have behavioral risk factors for infertility (e.g., smoking, drinking alcohol)? If so, do these relationships suggest future research needs?

Information to assess these relationships will aid OPA in carrying out its mission by increasing OPA's understanding of fertility knowledge and, together with findings from relevant studies in the literature, an OPA-sponsored environmental scan to assess the availability and scope of fertility education programs (conducted in 2018), and the NSFG, will serve to identify subgroups likely to benefit from improved fertility-related education, information, counseling, and services. OPA will review and incorporate survey findings into reproductive life planning, sexual risk assessment, and counseling for young adults with the goal of closing knowledge gaps, countering myths, and correcting misinformation about fertility-related behaviors. In addition, OPA will use the data from the survey to inform family planning and fertility/infertility education, counseling, and services that Title X offers. OPA will share findings through peer review publications and similar channels.

**Limitations and Strengths of Using Internet Panels for This Study**. These internet panels have limitations. The panels have low overall response rates and there is not sufficient information provided by the vendors to determine the extent to which non-response might be correlated with any of the factors in which OPA is interested in understanding. As such, even though the panel developer/owner (Ipsos) takes steps to reduce nonresponse (e.g., incentivization for recruitment and panel maintenance, and survey-specific incentives and nonresponse follow-up), the very low overall response rate in conjunction with the lack of information about non-response bias in the context of the factors of interest in this study mean that the OPA will treat the results as it would a large and diverse focus group. The main strengths of the Ipsos internet panel is that it supplies ready access to the eligible population and surveys can be implemented in a relatively short period of time (14–21 days) and at a low cost.

# 3. Use of Improved Information Technology and Burden Reduction

According to the Government Paperwork Elimination Act,<sup>15</sup> Federal agencies should consider an electronic option for every data collection. The *Fertility Knowledge Survey* is a web survey that will be self-administered at home on personal computers, tablets, or phones. Web surveys generally, and Ipsos web surveys specifically, have several advantages and disadvantages related to respondent burden, response rates, and data quality.

#### Advantages

• Internet access and hardware – Ipsos provides panel members with Internet access and hardware, as needed. In addition, Ipsos also offers technical support if panel members have difficulty accessing the internet or a particular survey or have problems with the equipment itself.

- **Convenience** Ipsos web surveys allow respondents to complete the survey at a time convenient for them and, within a specified period, allows the respondent to breakoff and return to complete the survey at a later time. This flexibility and convenience may reduce perceived burden of participating.
- Data quality In a web survey, skips can be programmed so that respondents only see questions relevant to them based on their responses to previous questions. In addition to programmed skips, the *Fertility Knowledge Survey* will display a message explaining the importance of a question if a respondent does not answer. In addition, the survey will display introductions, instructions, key definitions, and assurances in ways that aim to increase the accuracy of measuring key variables of interest, increase overall data quality, and reduce nonresponse.
- **Cost savings** A web survey offers significant cost savings over traditional telephone or in person surveys. Because a web survey does not involve interviewers and all ensuing requirements for interviewer training and quality control, data collection can be done more quickly and easily. Furthermore, invitations and nonresponse reminders sent by email are inexpensive ways to communicate with respondents and may help to reduce nonresponse. Finally, because web surveys capture the data electronically, there are no additional costs or quality concerns related to manual data entry.
- **Privacy and reduce risk of bias** A web survey offers the respondent greater privacy because it can be self-administered in a private setting of the respondent's choosing. Increased privacy, as compared to telephone interviewing, reduces vulnerability to socially desirable responses, particularly on sensitive subjects such as sexual and health behaviors. Web surveys are self-administered, and respondents do not speak to human interviewers as they would with telephone surveys.

#### Disadvantages

- **Response rates** Web surveys typically have lower response rates compared to mail (paper) and other survey modes.<sup>15</sup> According to Ipsos, the average cumulative response rate for KnowledgePanel<sup>®</sup> and Youth Panel, averaged over many surveys, is approximately 7%.<sup>16</sup> This 7% response rate reflects all stages, from original recruitment and empanelment to the final surveys. [Note: Of eligible panelists invited to complete the *Fertility Knowledge Survey*, 35% are expected to complete it (i.e., "expected cooperation rate").]
- Internet access or device problems Technical support for web surveys may not be able to resolve hardware or internet access issues in a timely way.
- **Confidentiality concerns** Web survey respondents may have concerns about the confidentiality of their responses to sensitive and other questions that are transmitted over the internet.
- **Respondent identity Web** surveys are unable to confirm with certainty that the selected respondent (or another family member) is the one that actually completes the survey.<sup>15</sup>

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

After assessing the available data sources, OPA has determined that the needed data or research do not exist, so primary data are required to explore fertility knowledge and related behaviors among young adults. Studies identified through a review of published and gray literature are limited in terms of target population, survey scope or content, small and geographically limited convenience samples, inclusion/exclusion criteria, and timeliness. Most recent U.S. studies focused on females and there were very few that studied American males (see Section A.1).

Guided by the research questions presented in Section A.2, OPA identified the following domains of inquiry, and topics within each one, to inform development of the *Fertility Knowledge Survey* instrument:

- **Domain 1-Fertility knowledge, awareness, and attitudes:** Fertility knowledge (e.g., facts, infertility risk factors, infertility myths, menstruation, fertile period), exposure and sources (all and trusted) of 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, willingness to use egg freezing to preserve fertility if childbearing were delayed, sexual activity/behaviors, contraceptive use, and knowledge/myths about the effect of contraception on future fertility;
- Domain 3-Access to fertility and other reproductive health information/services: Access to primary and specialized reproductive health care, use of reproductive health services, and discussions of fertility topics with medical providers;
- Domain 4: Health and risk behaviors associated with fertility knowledge, awareness, and attitudes: Self-perceived health status and fertility risk behaviors [e.g., smoking, weight, sexually transmitted diseases (STD) testing/diagnosis, and multiple sexual partners; and
- **Domain 5: Socio-demographic characteristics:** Demographic and socioeconomic characteristics, other background factors (e.g., religiosity, sexual orientation).

We identified existing surveys conducted by the U.S. Government and academic and private institutions in the U.S., Canada, Europe, and Australia and reviewed them for questionnaire items on the same or similar topics. Questions from existing surveys that addressed any of the five domains were evaluated and abstracted. Federal surveys included in the review were 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). To the extent possible and where appropriate, questions from existing federal surveys were used or adapted (e.g., modified wording or collapsing response categories) in constructing the *Fertility Knowledge Survey*. The questions on race and ethnicity adhere to OMB standards.

The NSFG (female and male) was a key source for selected questions related to pregnancy, childbearing, contraceptive use, and receipt of fertility or related reproductive health care.

The NSFG, however, contains no questions on knowledge of fertility and infertility. The *Fertility Knowledge Survey*, in contrast, focuses on fertility knowledge and related attitudes and behaviors. Consequently, the overlap between the *Fertility Knowledge Survey* and the *NSFG* is minimal.

# 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. <u>Consequences of Not Collecting the Information or Less Frequent Collection</u>

This is a one-time collection.

# 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. <u>Comments in Response to the Federal Register Notice/Outside Consultation</u>

**Public Comments in Response to the 60- and 30-Day Federal Register Notices (Attachment C).** A 60-day notice was published in the *Federal Register* on October 3, 2018 [Vol. 83, No. 192, pp. 49936-37]. A 30-day notice was published in the *Federal Register* on March 25, 2019 [Vol. 84, No. 57, pp. 11112-13]. No public comments were received in response to either notice.

**Consultation with Subject Matter Experts and RTI Survey Methodologists.** In developing the survey instrument, OPA consulted with three external fertility experts, substantive experts, and survey methodologists 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 the definitions of fertility and infertility to be used in the survey and selected questions pertaining to fertility knowledge and fertility-related health services and discussion topics. In *Exhibit 1*, we present the following information for each identifiable non-OPA stakeholder: year of consultation; name, title, and affiliation; and phone and email contact information.

Years	Name/Title/Affiliation	Phone/Email
2018-2019	<b>Rebecka Lundgren, PhD, MPH</b> Deputy Director and Research Director Institute for Reproductive Health Georgetown University	(202) 687-7969 lundgrer@georgetown.edu
2018	<b>Judith Daniluk, PhD, Professor</b> University of British Columbia	(604) 822-5768 judith.daniluk@ubc.ca
2018-2019	<b>Rashmi Kudesia, MD, MSc, FACOG</b> Fertility Physician, Houston IVF	(248) 225-4127 <u>rashmi.kudesia@gmail.com</u>
2018-2019	Christina Fowler, PhD, Project Director RTI International	(919) 316-3447 <u>cfowler@rti.org</u>
2018-2019	Helen P. Koo, PhD, Senior Research Demographer RTI International	(919) 493-1207 hpk.contractor@rti.org
2018-2019	Emily Geisen, MS, Senior Survey Methodologist and Manager of RTI Cognitive/Usability Laboratory RTI International	(919) 541-6566 <u>egeisen@rti.org</u>
2018	<b>Tim Flanigan, MA, Senior Survey Methodologist</b> RTI International	(919) 485-7743 <u>tsf@rti.org</u>

Exhibit 1-List of Individuals that Provided Extensive Review and Feedback on the Fertility Knowledge Survey

**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 cognitive and usability testing is described in more detail in Section B.4.

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. 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; defining vague terms and phrases; revising the instructions for true/false statements; and bolding or underlining words for emphasis.

#### 9. <u>Explanation of Any Payment/Gift to Respondents</u>

As presented in **Exhibit 2**, respondents to the Fertility Knowledge Survey will receive a general incentive for completing the survey and some will also receive an incentive specific to the Fertility Knowledge Survey (KnowledgePanel<sup>®</sup>).

**General incentives.** Ipsos provides general incentives to panel 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<sup>®</sup> or YouthPulse panelists and are not specific to their participation in the *Fertility Knowledge Survey*. For KnowledgePanel<sup>®</sup> members lacking an Internet device, Internet service, or both, Ipsos provides as an incentive one or both, as needed. For KnowledgePanel<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> members who complete a survey of 16 minutes or longer are entered into a sweepstakes.<sup>a</sup> Per the participation terms of YouthPulse Panel, panel members receive \$10 per completed survey and no additional incentives; Ipsos determined that provision of Internet devices or services was not needed for this group. YouthPulse Panel members receive their payment in check form.

Panel	General Incentive(s)	Study-Specific Incentive
KnowledgePanel <sup>®</sup>	Equipment (e.g., laptop)	\$5 (equivalent in points=5,000)
Member who does	Internet access	
not own a personal		
device or have		
internet		
<b>KnowledgePanel</b> <sup>®</sup>	1,000 points	\$5 (equivalent in points=5,000)
Member who owns a	Sweepstakes incentive <sup>a</sup> (survey $\geq$ 16	
personal device and	minutes)	
has internet access		
YouthPulse Panel	\$10	\$0

Exhibit 2-General and Study-Specific Incentives by Ipsos Panel

**Incentives specific to this data collection.** In addition to the general incentives described above, KnowledgePanel<sup>®</sup> 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 18–19 or males 25–29 years of age) 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 human 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*) and has received a Certificate of Confidentiality (CoC) (*Attachment K*).

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: \$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.

**Privacy.** The Fertility Knowledge Survey instrument does <u>not</u> collect any additional personally identifiable information (PII) from respondents than is already held by Ipsos. Ipsos is bound by the terms of the CoC and will keep the data private to the extent allowed by law. When the survey is completed, Ipsos will provide the data analysis contractor (RTI International) a data file that contains no PII (de-identified).

Ipsos staff with access to panelists' PII have no access to panelists' survey responses and vice versa. During recruitment of the 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) <u>solely</u> for purposes of conducting its research business, which includes pre-qualifying members or households for surveys, communicating with panel members, and ensuring a statistically 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 <u>separate</u> database from completed questionnaires and computerized data files used for analysis.

The survey response data are identified only by an incremented ID number. The following attachments present Ipsos's privacy-related assurances to panel members and other statements: The Deal: Your Rights and Responsibilities as a KnowledgePanel<sup>®</sup> Member (**Attachment H**), Privacy Policy for KnowledgePanel<sup>®</sup> Members (**Attachment I**), and Statement of Ipsos' Commitment to Privacy and Data Protection (**Attachment J**).

Regarding assurances of privacy provided to survey respondents, the survey invitation and consent form (*Attachments E* and *F*), provide panelists with the following assurances:

- The survey will <u>not</u> 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 (*Attachment K*) and the extent to which the CoC protects participant privacy. The specific CoC-related statement is as follows:

**Consent Form (Attachment F):** 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 a server that is backed up nightly and to which only authorized staff have access. The Statement of Ipsos' Commitment to Privacy and Data Protection is found in Attachment J.

With regard to assurances of confidentiality provided to survey respondents, the consent form (*Attachment F*) and the FAQ included in the invitation (*Attachment E*) assure respondents that Ipsos has processes in place to keep survey responses confidential and that answers will be transmitted and saved in a secure way to prevent unauthorized access, loss, or misuse. The assurance acknowledges that the confidentiality of the answers transmitted on the internet cannot be absolute.

# 11. Justification for Sensitive Questions

While a primary focus of the *Fertility Knowledge Survey* is to collect data to explore 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 OPA to explore and identify study subgroups with differing levels of fertility knowledge, and (b) increase the practical utility of findings by identifying subgroups that are likely to need enhanced or increased OPA efforts to improve fertility knowledge.

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:

• The Invitation letter and consent form [*Attachments E* and *F*] 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 form 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. <u>Estimates of Annualized Burden Hours (Total Hours and Wages)</u>

# 12A. Estimated Annualized Burden Hours

The estimated annualized hour burden of responding to this information collection is **1,005 hours**, or a weighted average of **20 minutes (.33 hours)** per respondent (see **Exhibit 3**). 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.

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 Survev	3,016	1	20/60	1,005*

Exhibit 3-Estimated Annualized Burden Hours	(*rounded down)
	(

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. The online survey will be programmed to display only questions that are relevant to the respondent based on responses to prior questions. Therefore, 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 (smoking or drinking).

# 12B. Estimated Annualized Respondent Cost Burden

The estimated total annualized labor cost to complete the *Fertility Knowledge Survey* is \$17,870, or an average of \$5.93 per respondent (see *Exhibit 4*). 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.<sup>17</sup> 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.

	Number of	Total Hour	Hourly	Respondent
Type of Respondents	Respondents	Burden	Wage Rate	Cost
Female				
18- 24 years	865	288	\$12.78	\$3,681
25- 29 years	865	288	\$20.60	\$5,933
Male				
18- 24 years	643	214	\$13.20	\$2,825
25- 29 years	643	214	\$25.38	\$5,431
Total	3,016			\$17,870

Exhibit 4-Estimated Annualized Cost to Respondents for Information Collection

\*Rounded down to accommodate rounding error

# 13. <u>Estimated Annualized Respondent Nonlabor Cost Burden</u>

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

# 14. <u>Annualized Cost to Federal Government</u>

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 5*) for the two-year period of the MITRE contract (with subcontractors RTI and Ipsos).

#### Exhibit 5-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. <u>Plans for Tabulation and Publication and Project Time Schedule</u>

#### 16A. Plans for Tabulation and Publication

The descriptive and exploratory analysis of the survey data will address the research questions presented in Section 2 and is planned to proceed as follows:

- First, we will produce frequency and percentage distributions and descriptive statistics for every item in the questionnaire for women and men, and for ages 18-24 and 25-29 within each sex.
- Second, to ease analysis, we will construct composite variables and scales for relevant items. Most important are the many items measuring knowledge of fertility and infertility risk factors.
- Third, for key composite indicators of fertility knowledge and infertility risk factors, we will examine the percentage distributions of these items for females and males, and within each sex, for ages 18-24 and 25-29.
- Similarly, we will examine the percentage distributions of individual and composite knowledge measures of groups of individuals with different fertility-related attitudes and behaviors (e.g., childbearing attitudes and plans, reproductive behaviors such as contraceptive use, access to and use of health care, sources and preferred sources of fertility information) and with different infertility risk factors (e.g., smoking, weight). These analyses will identify groups of individuals with low fertility knowledge and thus who are likely to need improved or increased fertility-related education, information, counseling, and services.

The survey findings will be presented to OPA in the form of an internal report. Although the information to be collected and the results are not considered to be influential on policy or programming, for any OPA activity that uses data from the *Fertility Knowledge Survey*, an OPA or other HHS staff with appropriate expertise in survey data will perform a methodological review to ensure that appropriate methods have been used and reported, and that there is an appropriate discussion of the limitations of the data, methods, and procedures.

# 16B. Project Time Schedule

*Exhibit 6* presents the timeline for activities related to data collection, analysis, and dissemination.

Activity	Expected Date of Completion
Incorporate final, OMB approved edits to the online survey	Within 1 month after OMB approval
Conduct final quality control check of programmed	2 months after OMB approval
Field online survey	2 months after OMB approval
Complete survey	2-3 months after OMB approval
Prepare de-identified and weighted dataset and documentation	3 months after OMB approval

Exhibit 6-Timetable for Data Collection, Analysis, and Publication

Activity	Expected Date of Completion
Data analysis	3-4 months after OMB approval
Prepare internal findings report	4 months after OMB approval

# 17. <u>Reason(s) Display of OMB Expiration Date Is Inappropriate</u>

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

There are no exceptions to the certification.

- <sup>1</sup> The definition of fertility knowledge is adapted from the Georgetown Institute of Reproductive Health's fertility awareness definition found here: Aumack-Yee K, Hilliard S. Fertility Awareness Across the Life Course. Washington, DC: Institute for Reproductive Health, Georgetown University; 2013.
- <sup>2</sup> 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.
- <sup>3</sup> U.S. Census Bureau. (2017). Historical Marital Status Tables. Accessed from <u>https://www.census.gov/data/tables/time-series/demo/families/marital.html</u>
- <sup>4</sup> Daugherty, J and Martinez, G. (2016). Birth Expectations of U.S. Women Aged 15-44. NCHS Data Brief, NO. 260, October 2016. Accessed from <u>https://www.cdc.gov/nchs/data/databriefs/db260.pdf</u>
- <sup>5</sup> 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 <u>https://www.cdc.gov/nchs/data/databriefs/db232.pdf</u>
- <sup>6</sup> Centers for Disease Control and Prevention. (2019). Infertility FAQs. Accessed from <u>https://www.cdc.gov/reproductivehealth/infertility/index.htm</u>
- <sup>7</sup> 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.
- <sup>8</sup> Centers for Disease Control and Prevention. (2017). STDs & Infertility. Accessed from <u>https://www.cdc.gov/std/infertility/default.htm</u>
- <sup>9</sup> EMD Serono. (2011). In the Know: Fertility IQ 2011 Survey. Accessed from https://www.npr.org/assets/news/2011/11/FertilityWhitePaper\_Final.pdf
- <sup>10</sup> Lundsberg, L.S., et al. (2014). Knowledge, attitudes, and practices regarding conception and fertility: a populationbased survey among reproductive-age women. *Fertility and Sterility*, 101(3):767-774.
- <sup>11</sup> 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.
- <sup>12</sup> 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.
- <sup>13</sup> Polis, CB and Zabin, LS. (2012). Missed conceptions or misconceptions: Perceived infertility among unmarried young adults in the United States. Perspectives in Sexual and Reproductive Health, 44(1):30-38.
- <sup>14</sup> Office of Population Affairs. (2019). Mission. Accessed fromhttps://www.hhs.gov/opa/about-opa/mission/index.html
- <sup>15</sup> The Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII, was signed into law on October 21, 1998.
- <sup>16</sup> M. Lawrence (Senior Vice President Ipsos) personal communication, August 6, 2019.
- <sup>17</sup> Bureau of Labor Statistics. Usual Weekly Earnings of Wage and Salary Workers. Second Quarter 2018. BLS Economic News Release July 17, 2018. Accessed from <u>https://www.bls.gov/news.release/pdf/wkyeng.pdf</u>