# 2014 Health Center Patient Survey Pretest

Supporting Statement
Request for OMB Review (SF83i)

Submitted by
Health Resources and Services Administration
U.S. Department of Health and Human Resources
April XX, 2013

# Supporting Statement A

# Health Center Patient Survey

# OMB Control No. 0915-XXXX

**Terms of Clearance: None.**

**A. Justification**

**1. Circumstances Making Collection of Information Necessary**

**a. Purpose of this Submission**

This submission requests Office of Management and Budget (OMB) clearance to conduct the Health Center Patient Survey Pretest (HCPS; OMB No. xxxx-xxxx). The pretest is being conducted by RTI International for the U.S. Department of Health and Human Services (DHHS) Bureau of Primary Health Care (BPHC) within the Health Resources and Services Administration (HRSA), under contract number GS10F0097L\HHSH250501200096G. This submission describes the procedures and instruments planned for the pretest data collection effort. An additional OMB package will be submitted prior to the full-scale study implementation which will include procedures for the main study taking into account the results of the pretest.

The mission of HRSA is to improve heath and achieve health equity through access to quality services, a skilled health workforce, and innovative programs. HRSA's Bureau of Primary Health Care administers the Health Center Program, as authorized by section 330 of the Public Health Service (PHS) Act, 42 U.S.C. 254b, as amended. Health Centers (HCs) improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. The Health Center Program administered by BPHC supports the provision of community-based preventive and primary health care services to the medically underserved and to vulnerable populations with special needs, through Section 330 grants to HCs and community

organizations. The populations include, but are not limited to: poor and near poor, homeless, public housing residents, migrant and seasonal farm workers, at-risk women, minorities, persons with HIV/AIDS, uninsured and underinsured, and non-English speakers.

The Health Center Patient Survey (herein referred to as the HCPS) will collect in-depth information about HC patients such as their health status, the reasons they seek care at HCs, their diagnoses, the services they utilize at HCs and elsewhere, the quality of those services, and their satisfaction with the care they receive. The HCPS will be conducted in two stages: (1) a pilot survey or pretest of the survey instrument, survey sampling methodologies and procedures, and (2) the main survey, consisting of a personal interview of a stratified random sample of patients of the Health Center program. Both the pretest and main study will sample patients of Section 330-funded HCs. The HCPS builds on previous periodic User-Visit Surveys which were conducted to learn about the process and outcomes of care in Community Health Center (CHC), Health Care for the Homeless (HCH), Migrant Health Center (MHC), and Public Housing Primary Care (PHPC) projects. In addition, the HCPS will include patients from different racial/ethnic backgrounds, including Chinese, Koreans, and Vietnamese, subgroups not included in the previous surveys. The original questionnaires were derived from the National Health Interview Survey (NHIS) and the National Ambulatory Medical Care Survey (NAMCS) conducted by the National Center for Health Statistics (NCHS). Conformance with the NHIS and NHAMCS allowed comparisons between these NCHS surveys and the previous CHC and HCH User/Visit Surveys. The present HCPS instrument was developed using a similar questionnaire methodology to that used in the past, and will allow comparisons for HC projects with the previous User/Visit survey data, including monitoring of process outcomes over time. Additional analysis capabilities are elaborated upon in Section A2.

Prior to the conduct of the main HCPS, a small-scale pretest will be conducted to test main study implementation materials and procedures and identify potential questionnaire problems. The pretest will include 69 in-person cognitive interviews conducted in English, Spanish, Chinese (Mandarin and Cantonese), Vietnamese, and Korean. Specifically, along with testing operational materials and procedures, the interviews will focus on identifying any problems with instrument question wording, instructions, and assumptions as well as evaluating timing and the flow of the questions. Pretest results will drive procedural and questionnaire improvements prior to main study implementation. After the pretest, the HCPS main study will be conducted and will include a nationally representative sample of patients from all four types of Section 330-funded HC programs.

The data gathered from the pretest will ensure proper administration of the main survey. The data from the main HCPS will facilitate the Bureau’s mission to improve the health of the nation’s underserved communities and

ensure access to high-quality primary health care services. The data generated from these surveys will assist BPHC to assess how well HRSA-supported health care sites are able to meet health care needs, guide planning decisions, and determine the extent to which HCs meet the needs of underserved populations, as well as how patients perceive the quality of their care. Additionally, the data resulting from the survey will serve as a complementary source of data that are not routinely collected from other BPHC data sources. Furthermore, data collected from this round of the Patient Survey will serve as a baseline to assess the impact of Affordable Care Act implementation on HC patients. The Patient Survey incorporates all measurement constructs from the Consumer Assessment of Health-care Providers and Systems (CAHPS) explicitly mentioned in H.R. 3590 (Affordable Care Act) for evaluating quality of care and patient satisfaction.

BPHC does not routinely collect this type of information from HC sites and these data are not available from the Uniform Data System or any other source. The Patient Survey results are essential to compare HC procedural, health care and health outcome data with other national surveys (e.g., National Health Interview Survey (NHIS)) and to conduct analyses that will enable comparisons of HC patient characteristics, health-related behaviors, health service utilization, health conditions, patient satisfaction, and patient access to care with patients in other health care settings. In addition, this iteration of the Patient Survey will be aligned with Section 4302 of the Affordable Care Act[1] (ACA) and the 2011 race and ethnicity data collection standards specified by the Secretary of the U.S. Department of Health and Human Services.[2] This alignment will provide unprecedented detailed information on the diversity of HC patients, their health insurance, and their health service use and experience than any other Patient Survey. To meet the HHS standards for data collection will require the Patient Survey to select a sample of patients from the 50 states (and the District of Columbia), increase its historical analytical sample size from 4,500 to 6,600, utilize respondent oversampling methods, and conduct the survey in four languages other than English.

## Legislative Authorization

The HCPS pretest is conducted by the Bureau of Primary Health Care's Office of Quality and Data within the Health Resources and Services Administration in close consultation with other offices and organizations within and outside the U.S. Department of Health and Human Services. The HCPS pretest is authorized under Sections 330 and 331 of the Public Health Service Act (USC 254 b,d). A copy of this section of the legislation is shown in Appendix A.

## Prior and Concurrent Related Studies

The HCPS builds on the Community Health Center Patient Survey conducted in 2009 (OMB No. 0915-0326), the Health Care for the Homeless User/Visit Surveys conducted in 2003 (OMB No. 0915-0274), the 2002 Community Health Center and National Health Service Corps Site User/Visit Survey (OMB No. 0915-0186), and the 1995 Community Health Center

1 http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=208
2 http://www.hhs.gov/news/press/2011pres/10/20111031b.html

User/Visit Survey (OMB No. 0915-0185). Data collection for the HCPS will be conducted in 2013 (pretest) and 2014 (full scale).

### b. Study Design

The HCPS pretest will include cognitive interviews of patients of Section 330-funded HCs. Specifically, the pretest will encompass 69 in-person cognitive interviews, 15 of which will be conducted at 2 HC sites (one urban and one rural). Three rounds of cognitive pretesting interviews will be conducted. The necessity of three rounds of interviews is to (1) thoroughly test the English version of the questionnaire; (2) introduce and test the four language translations (Spanish, Chinese, Vietnamese and Korean) of the questionnaire along with the English version following programming as computer-assisted personal interviews (CAPI); and (3) retest each language following revisions from round 2. This approach will provide an extensive opportunity to gauge the comprehension of the questionnaire in multiple languages while assessing the usability of the computerized instrument. In addition, interviews will be conducted with the following three types of respondents:

- adults aged 18 or older reporting on their own experiences (i.e., self-reporting adults);
- parents or guardians of children (aged 12 and younger) selected to participate who are reporting on their children's experiences (i.e., proxy interviews with adults); and
- adolescents aged 13 to 17 who are accompanied by a parent or guardian reporting on their own experiences (i.e., accompanied adolescents).

In the first round of the pretest, the focus will be on the sampled participant's comprehension of the English version of the questionnaire. One rural and one urban health center will be identified as the location to conduct the pretest. These health centers will be selected based on their proximity to Durham, North Carolina to minimize travel to and from the centers. Once identified, the directors of each facility will be approached to help with the pretest by providing a location where we can recruit and interview patients. In total, 8 participants will be recruited from these two facilities. An additional 8 participants will be recruited through advertisements posted in community forums such as Craigslist, postings of flyers at the local HCs, community centers, and libraries.

Each participant will receive approximately one-half of the questionnaire using a paper and pencil interview (PAPI). A debriefing meeting comprising the research team and cognitive interviewers will follow the completion of all 16 interviews to

discuss recommendations from the first round of testing. The questionnaire will then be revised based on these recommendations.

Following the first round of testing, the questionnaires will be translated into Spanish, Korean, Chinese (Mandarin and Cantonese), and Vietnamese and programmed into CAPI. The second round of cognitive interviews will be conducted on 32 participants: 6 in English, 8 in Spanish, 6 in Korean, 6 in Chinese (three in Mandarin and three in Cantonese), and 6 in Vietnamese. Half of the English and half of the Spanish interviews will be conducted at the urban and rural facilities selected in the first round of testing. The remainder of the interviews, including all of the Korean, Chinese, and Vietnamese interviews will be recruited through advertisements posted in community forums such as Craigslist, postings of flyers at the local HCs, community centers, and libraries. The main reason for this split recruitment approach is due to the complexity of locating Korean, Chinese (Mandarin and Cantonese), and Vietnamese patients while visiting the HCs to conduct on-site recruitment.

Each sampled participant will be administered the entire questionnaire with skip logic employed so they will only receive questions that are relevant to them. A debriefing meeting comprising the research team and cognitive interviewers will follow the completion of all 32 interviews. The questionnaire will be revised based on recommendations from the debriefing.

A third round of 21 cognitive interviews will be conducted to test revisions made following the second round of testing and continue to assess the functionality of the computerized instrument. In round three, 6 interviews will be conducted in English, 5 in Spanish, 4 in Chinese (two in Mandarin and two in Cantonese), and 3 each in Vietnamese and Korean. Following the conduct of round 3 interviews, a debriefing meeting comprising the research team and cognitive interviewers will be conducted. The questionnaire will further be revised based on recommendations from the debriefing.

All of the interview participants in the third round will be recruited using a standard call for participants through local advertising. These interviews will be conducted outside of the HC setting (e.g., at the participant's home, in community centers or libraries).

For on-site interviews, RTI project staff will initiate telephone contact with these sites to solicit their participation in the study. The RTI project staff will answer any questions posed by site staff and report any difficulties to the RTI project management staff. RTI project staff will be responsible for arranging and conducting site staff trainings. These trainings will last approximately 1.5 hours and will be conducted on-site with key stakeholders and administrative staff at each site immediately before data collection begins. RTI anticipates that on average two staff members per site will attend. Particular attention will be paid to the role of the site staff in sample selection for the patient survey, appropriate use of project-provided recruitment materials, role of site staff as advisors during the administration of informed consents to unaccompanied minors, role of site staff as recipients of referrals for mandatory reporting issues, and the importance of privacy.

Patients will enter the site and register with the receptionist for services. The receptionist will select patients on a flow basis according to the detailed study sample selection protocols to ensure the selection of a random sample of patients. Specifically, the receptionist will select the first patient registered after the RTI staff member informs the receptionist that he or she is ready for the next interview. The receptionist will read a brief recruitment script to the patient (or his or her parent or guardian, for selected children) and give him or her a study hand-out which will provide patients with information about the study, how long the interview takes, who to contact for more information on the study, and of the $50 incentive (or non-cash equivalent) they will receive for their participation. If the selected patient is interested in participating or has questions about the study, she or he will approach the RTI team member. The RTI staffer will work to gain cooperation and then take interested participants to the designated private location at the site to begin the screening, informed consent, and interviewing process. The RTI staff will ask the participant some initial screening questions from the Participant Screening Form to determine the patient's eligibility for the study (which includes determining patient type), and if he or she is eligible, administer the appropriate informed consent and continue with the interview.

RTI staff will employ one of the following informed consent procedures depending on (1) the age of the respondent and (2) if the respondent is 13 to 17 whether he or she is accompanied by an adult. The respondent's answers to the questions included on the Participant Screening Form will inform which procedures the RTI staff member will follow.

- **Self-consent for adult respondents aged 18 and older**—RTI staff will present the subject with a copy of the Adult Survey Participation Consent Form and read it aloud. Afterward, the subject will be invited to ask any questions about the study. Respondents who agree to participate will then be asked to sign the appropriate consent form; if respondents cannot sign their names they will be asked to make a mark for their names.
- **Parental/guardian consent for child respondents aged 12 and younger (proxy interviews**)—RTI staff will present the subject with a copy of the Parent/Guardian Participation in Proxy Interview for Accompanied Children Consent Form and read it aloud. Afterward, the subject will be invited to ask any questions about the study. Respondents who agree to participate will be asked to sign the consent form; if respondents cannot sign their names they will be asked to make a mark for their names.
- **Parental/guardian consent and adolescent assent for respondents aged 13 to 17 who are accompanied by a parent/guardian**—RTI staff will first approach the parent/guardian and obtain parental consent on the Parent/Guardian Permission Form for Adolescent Participation with the adolescent present. RTI staff will

next request the parent/guardian go to a waiting area therefore allowing the interviewer to privately obtain youth assent on the Minor Participant Assent Form.

- The consent/assent forms will be read both to the parents and the adolescent. Both parents and adolescents will be invited to ask any questions. Parents/respondents who agree to participate will be asked to sign the consent form; if parents/respondents cannot sign their names they will be asked to make a mark for their names.

All participants will be provided with an unsigned copy of the consent form to take with them after completion of the interview or with a signed photocopy instead, should they prefer. In the "Parental/guardian consent and adolescent assent for respondents aged 13 to 17 protocol, a copy of the parent/guardian consent form will be given to the parent/guardian and a copy of the assent form will be given to the participant. After the administration of the informed consent, the cognitive interview will begin.

Cognitive methods provide important tools for examining the thought processes that affect the quality of answers provided to survey questions. Cognitive interviewing methodologies including "think aloud" interviewing and probing techniques. A "think aloud" interview is one in which the respondent is instructed to tell the interviewer everything that he or she is thinking about in answering a survey question. Probes can be concurrent or retrospective and can be prepared ahead of time or spontaneous. In concurrent probing, the probes are asked at the same time the subject answers the questions; in retrospective probing, the probes are asked during a debriefing session after the interview is over. Prepared probes will be designed prior to the pretest interview, while spontaneous probes will be administered during the interview by the interviewer.

The HCPS questionnaire to be tested has been developed with BPHC and a Technical Advisory Committee. The prepared probes will be used in conjunction with the draft questionnaire. The discussion questions will include a small set of open-ended questions that will be asked of pretest respondents during and after completing the interview. The discussion questions will focus on the following issues:

- respondents' perceptions of the recruitment materials, consent forms, and overall study procedures;
- items that respondents found difficult to answer;
- items that respondents did not feel that others would answer truthfully;
- respondents' perceptions of the length of the survey; and
- respondents' perceptions of the proposed incentive.

If at any time the privacy of the interview setting is compromised, the interviewer will pause the interview until privacy can be reestablished, rescheduling as necessary. After the interview is completed each respondent

will be given a $50 incentive payment (or noncash equivalent) and asked to initial a receipt.

Once pretest data collection is complete, RTI project staff will prepare a report including timing data, problems encountered, and recommendations for change. All data collection materials that are shown or read to respondents will be available in English, Spanish, Chinese (Mandarin and Cantonese), Vietnamese, and Korean.

## 2. Purpose and Use of Information Collection

The HCPS is unique in its effort to capture national, person-level data from patients of all types of Health Center Program grantees. The data collected from the HCPS pretest will be used to test the main study data collection procedures and materials and revise the survey instrument. Instrument modifications may involve eliminating poor questions, redesigning questions and response categories, providing transitional statements, adding notes for the interviewer, or adding further clarification to the respondent. All pretest data gathered will be destroyed once the redesign is completed. The pretest will, in turn, assist in ensuring a successful main survey implementation and contribute to BPHC's overall project goals. As noted earlier, with the main HCPS, BPHC aims to:

- Gather nationally representative data about the patients of the CHC, MHC, HCH, and PHPC programs and the services they obtain;
- Enable comparisons of care received by HC patients with care received by the general population, as measured by NHIS and other national surveys; and
- Gather information which will assist policymakers and BPHC staff to:
  - assess how well HRSA-supported HC are currently able to meet health care needs,
  - identify areas for improvement and guide planning decisions, and
  - complement data that are not routinely collected from other BPHC data sources.

The specific BPHC priorities for analysis will be comparisons of HC patients with patients served in other primary care settings with respect to:

1. Access to care
2. Health disparities
3. Health conditions
4. Quality of care
5. Care coordination
6. Patient experience

Comparisons will be made with results from national surveys, and with results from the 2009 Patient Survey. The data elements included in the HCPS instrument are collected through the following 17 modules administered to patients:

A. Introduction

B. Access to Care

C. Routine Care
D. Conditions
E. Conditions follow-up
F. Cancer Screening
G. Health Center Services
H. Health Insurance
I. Prescription Medications
J. Dental
K. Mental Health
L Substance Abuse
M. Prenatal Care / Family Planning (Females aged 15-49)
N. HIV Testing
O. Living Arrangements
P. Neighborhood Factors
Q. Income and Assets
R. Demographics

3. **Use of Improved Information Technology and Burden Reduction**

RTI will conduct three rounds of cognitive pretest interviews. The first round will be administered using PAPI. Each participant will receive approximately one-half of the questionnaire. The second and third rounds will be administered using CAPI. The CAPI approach offers several advantages that keep participant burden at a minimum while ensuring collection of high-quality data. First, the questionnaire is somewhat complex and involves numerous skip patterns and screening questions. These are easily and quickly performed by the computer upon completion of CAPI programming. In addition, the CAPI instrument detects erroneous and inconsistent responses, increasing data accuracy and validity. The use of CAPI, therefore, will enable the interview to be completed in less time and with more accuracy than the PAPI.

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

The information to be collected through the HCPS is unique to this survey and cannot be obtained elsewhere.

5. **Impact on Small Businesses or Other Small Entities**

This project will not have a significant impact on small businesses or small entities. Information regarding the best time to interview clients, policies regarding minors' participation, and preferences regarding respondent remuneration type will be discussed with site staff in order to accommodate grantees and sites.

**6. Consequences of Collecting the Information Less Frequently**

The HCPS pretest will be used to conduct cognitive interviews that gauge the comprehension of the questionnaire in multiple languages, assess the usability of the computerized instrument, and to test data collection procedures to be employed in the main study. Each patient sampled in the pretest will only participate in this survey once.

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

This information collection fully complies with 5 CFR 1320.5(d)(2).

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

**Section 8A:**

A 60-day Federal Register Notice was published in the Federal Register on January 11, 2013, Vol. 78, No. 8; pp. 2411-12. A copy of the notice is included in Appendix B. One public comment was received on January 12, 2013 requesting for a copy of the data collection plan and the proposed instrument. The documents were sent to the commenter within one week from the request.

**Section 8B:**

In recognition of the significance of the HCPS pretest and main survey data collection efforts, several strategies have been incorporated into the project work plan that allow for the critical review and acquisition of comments relating to project activities, interim and final products, and projected and actual outcomes. These strategies include consultations with persons and organizations both internal and external to the BPHC, the U.S. Department of Health and Human Services, and the Federal government.

Specifically, a Technical Advisory Committee (TAC) was assembled for the HCPS. A list of the participants on the project's TAC is provided in Appendix C. Membership represents a broad spectrum of grantee staff members, representatives from coalitions/associations, nationally recognized research experts, and Federal government employees. Committee members serve as expert reviewers on the instrument design and analysis plans. Individual members will be consulted throughout the survey development process by telephone and participate (if available) in in-person meetings. The TAC reviewed the draft pretest data elements during an initial in-person meeting in January 2013. Written and/or verbal responses were received from all of those consulted and the recommendations were incorporated into the survey and instrument design to the extent possible.

Research Triangle Institute (RTI) staff has been extensively involved in the statistical design of the survey and in the development of the data collection forms. The pretest and full-scale survey implementation for the HCPS will be conducted by RTI.

## 9. Explanation of any Payment/Gift to Respondents

During the HCPS field test, participants will be offered a $50 cash incentive (or noncash

equivalent) for taking part in the pretest interview. This is a standard incentive amount provided to respondents for the burden placed on them. Sites will be given the option of requesting that RTI supply a cash or noncash incentive to the participants. If a site prefers noncash incentives, RTI will assist in determining an appropriate alternative. Examples of noncash options include food vouchers, telephone cards, personal hygiene bags, and movie tickets. Interviewers will be required to complete a receipt for all incentives (whether they are cash or cash equivalent) and have the respondent sign the receipt.

## 10. Assurance of Confidentiality Provided to Respondents

Participating individuals and institutions will be informed that the information provided in the HCPS will be kept secure and will be protected. Data collected will be in total conformity with HRSA's standards for protecting personally identifiable information on individuals. Consistent with the Privacy Act of 1974, BPHC's contractor will not provide participant names or information about participants to persons who are not part of the survey team.

The plan for maintaining privacy is outlined in a Data Security Plan (Appendix D) created by BPHC's contractor. Some highlights from the Data Security Plan include (1) maintaining safeguards to minimize the possibility of inadvertent disclosure, (2) conducting extensive training regarding privacy, and (3) obtaining privacy pledges from all personnel who will have access to individual identifiers.

### Minimizing Inadvertent Disclosure

To avoid someone obtaining the information provided to RTI during the interview, RTI will conduct the interview in a private location where answers cannot be overheard. In addition, RTI will create an identification (ID) number which will be used instead of the respondent's name, which will prevent anyone from identifying who the answers came from. Finally, the patients will be selected for the study using onsite recruitment procedures that will protect the patients' identity before they consent to participate in the study. The patient selection procedures are also designed to address HIPAA privacy concerns. Namely, the interviewer will not be allowed to approach any of the site's patients nor obtain any information about the patients unless the selected patient initiates contact with the interviewer. The consent form accompanying the questionnaire will serve to inform respondents that that their participation is voluntary and will reiterate the protection of survey information.

All of the information collected will be kept private. Some respondent information will be collected and stored on paper. RTI staff will carry paper forms for recording respondent consent, receipt of incentives, and the actions which took place with each case including the current case status (via a contact summary report form). BPHC and RTI designed the data collection protocol to minimize the amount of identifying information (i.e. information which could identify the respondent as a participant in the study) that is stored on paper forms. Only the consent form and the contact summary report form will include the respondent's personal information. The consent form will include the respondent's signature while the contact summary report form will include the respondent's case id and only if an appointment is set the respondent's first name, contact number, appointment location, and parent or guardian's name (if applicable). RTI has

specified physical safeguarding and shipping procedures for paper forms, and protocols for training RTI staff in the use of these procedures. Additional details regarding the procedures are included below.

**Safeguarding Physical Materials in the Field**

RTI staff will be trained on the importance of maintaining the privacy of all study materials containing case-specific information. Specific procedures designed to ensure that physical security of these items is not compromised include the following:

- When in the field, case materials must be kept with the interviewer or kept in a locked trunk. However, materials may not be left in the trunk overnight. No materials may be left visible in an unoccupied vehicle.

**Shipping Materials**

To prevent opportunities for data loss after an interview is completed, RTI staff will be held accountable for adhering to specified procedures for shipping materials to back to RTI:

- Completed consent forms, incentive receipts, and contact summary report form will be shipped to the Instrument Design Task Leader periodically. Completed questionnaires will also be sent to the Instrument Design Task Leader, but in a separate package.
- RTI staff will prepare a transmittal sheet and place it in the Federal Express package. The transmittal sheet contains the air bill number, name of the person who will receive the package, date the package is sent, and the case identification numbers of the case folders. RTI staff will keep a copy of the transmittal sheet. If a package is lost, an inventory of missing items is readily available.
- RTI staff will be instructed to send Federal Express tracking information via e-mail to the Instrument Design Task Leader each time they ship study materials to RTI. This e-mail must include a list of the items in the Federal Express package, the shipment date, the expected delivery date, the delivery address, and the tracking number. No respondent personally identifying information is included in these e-mails.
- Packages cannot include the name or acronym of the study anywhere on the package or on the shipping bill.

**Storage of Documents**

Paper forms will be received, logged, and stored by RTI's Instrument Design Task Leader in a controlled-access location.

- The Instrument Design Task Leader will train interviewers on procedures for receipt and storage of materials. This staff member (along with all project staff) will sign the project's Privacy Pledge Agreement.
- All documentation (e.g. consent forms, incentive receipts, contact summary report forms, and questionnaires) will be kept in a locked RTI cabinet and destroyed following the completion of the pretest and modification of the instrument for the main survey.

**RTI Staff Training/Privacy Pledges**

Comprehensive training on all data privacy and security protocols will be provided to RTI cognitive interviewing staff with particular emphasis on challenges to protecting privacy when conducting research in HC. The training will include detailed information on all data

privacy and security protocols, including requirements for safeguarding private information and shipment of private materials. Also included will be a description of RTI's disciplinary procedures for failure to follow project protocols, including those related to data privacy and security. RTI staff who violate protocols for protecting privacy and data security will be subject to RTI's disciplinary procedures including verbal warnings, written warnings, probation, and termination. All staff working on the project will be required to sign a Privacy Pledge.

**Additional Safeguards**

RTI maintains a standing Committee on Human Subjects to ensure that all Institute surveys of human populations comply with applicable regulations concerning informed consent, confidentiality, and protection of privacy. This group serves as RTI's Institutional Review Board (IRB) as required by law (45 CFR #46). RTI policy requires that the IRB independently review and approve the study design, instruments, and procedures, and monitor the study annually to ensure that respondents' rights are fully protected.

Study notification materials provided to patients will describe the voluntary nature of the HCPS and convey the extent to which respondent identifiers and all responses will be kept private. Similarly, the scripts to be read by interviewing staff will be very specific in the assurances made to respondents and contacts.

**Exceptions to the Assurance of Privacy**

It is possible a respondent may become uncomfortable or upset during the interview or experience some psychological stress. To ensure that patients understand their participation is voluntary and that they can take a break, skip any questions and/or refuse to participate at any time it is stated in the consent form and reviewed with the participant prior to questionnaire administration. However, it is important to note one exception to the assurance of privacy exists and is stated clearly during the informed consent process: "There is one important exception to this promise of privacy. If I learn during our talk that your life or health, or another person's life or health could be in danger, I am required to inform the clinic staff or the proper authorities." If a respondent becomes extremely distressed, expresses that he or she is considering suicide, expresses that he or she is considering harming another person, or discloses that he or she has been the victim of child abuse or neglect, interviewers will be trained to handle these types of critical incidents by following the critical incident protocol (Appendix E).

In addition, RTI will create a resource list which will be supplied to the respondents at the end of each interview with helpline numbers to be utilized as needed.

## 11. Justification for Sensitive Questions

The HCPS pretest instrument contains several items which may be viewed as "sensitive." Federal regulations governing the administration of these questions, which might be viewed as sensitive due to personal or private information, require (a) clear documentation of the need for such information as it relates to the primary purpose of the study, (b) provisions to respondents which clearly inform them of the voluntary nature of participation in the study, and (c) assurances of private treatment of responses. The following areas have been identified as potentially sensitive:

1. Questions on substance use and mental health status, and perceived need for and use of mental health and substance abuse services may be perceived as sensitive by some respondents. However, such information is important for understanding of the degree of unmet need for mental health and substance abuse services.
2. Questions on HIV testing status and HIV infection status may be perceived as sensitive by some respondents. However, such information is important for understanding the experiences of HC patients.
3. There is a question inquiring about the respondent's annual earnings and public assistance. The question is designed to obtain the most accurate response to annual income. However, respondents can elect to respond using an income range if they feel more comfortable.

As noted in the informed consent procedures detailed previously, prior to conducting the interview all respondents are informed about the voluntary nature of their participation and the private treatment of their survey responses. Additionally, when a series of sensitive questions appear in the survey, they will be preceded by a statement read to the respondent which reiterates the points discussed during the informed consent administration. Respondents will understand that they have the right to refuse any question that they do not feel like answering. They will also understand that refusing any question will not impact the care they currently receive from the health facility.

12. **Estimates of Annualized Hour and Cost Burden**

Burden estimates for the pretest data collection activities are provided in table 1, and estimated costs to respondents are presented in table 2.

**Table 1. Maximum estimated burden on respondents for the HCPS pretest**

| **SURVEY PRETEST** | | | | | |
|---|---|---|---|---|---|
| **Type of respondent; activity Involved** | **Number of respondents** | **Responses per respondent** | **Total number of responses** | **Burden per response (hours)** | **Total hour Burden** |
| **Grantee/Site Recruitment** | 2 | 3 | 6 | 3 | 18 |
| **Patient Recruitment (At clinic)** | 21 | 1 | 21 | .17 | 3.57 |
| **Patient Survey (Administered at clinic)** | 15 | 1 | 15 | 1.25 | 18.75 |
| **Patient Recruitment (Through local advertisements / flyers /** | 71 | 1 | 71 | .08* | 5.68 |

| | | | | | |
|---|---|---|---|---|---|
| **word-of-mouth)** | | | | | |
| **Patient Survey (Administered following local advertising)** | 54 | 1 | 54 | 1.25 | 67.5 |
| **Total Pretest** | 69 | | | | 113.5 |

*5 minute telephone screener to determine eligibility

**Table 2. Maximum estimated costs to respondents for the HCPS pretest**

| SURVEY PRETEST | | | |
|---|---|---|---|
| **Type of respondent; activity Involved** | **Total hour Burden** | **Rate per hour ($)** | **Total Cost ($)** |
| **Grantee/Site Recruitment** | 18 | 7.25 | 130.50 |
| **Patient Recruitment (At clinic)** | 3.57 | 7.25 | 25.88 |
| **Patient Survey (Administered at clinic)** | 18.75 | 7.25 | 135.94 |
| **Patient Recruitment (Through local advertisements / flyers / word-of-mouth)** | 5.68 | 7.25 | 41.18 |
| **Patient Survey (Administered following local advertising)** | 67.5 | 7.25 | 489.38 |
| **Total Pretest** | 113.5 | | 822.88 |

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no capital, startup, or operating costs to respondents for participation in the project. No equipment, printing, or postage charges will be incurred to respondents.

**14. Annualized Cost to Federal Government**

Estimated annual costs to the Federal government for the HCPS are presented in table 3. These are based on federal staff time to monitor the performance of the pre-test and surveys, and to participate in the development and dissemination of results. An annual breakdown of the contract costs is provided in table 4.

## Table 3. Total annual costs to BPHC for the HCPS field test and full-scale implementation

| Costs to BPHC | Amount (in $) |
|---|---|
| Field Test (Year 1) Salaries | 45,000.00 |
| Full-scale Study (Years 2 and 3) Salaries | 90,000.00 |
| Total annual costs (Average Salaries for years 1, 2, and 3) | $45,000.00 |

**Table 4. Annual contract costs for the HCPS implementation**

| HCPS Project Year | Cost ($) |
|---|---|
| 1 | 656,541 |
| 2 | 2,779,941 |
| 3 | 2,626,396 |
| Total | 6,062,878 |

The total annual cost to the Federal Government is $2,065,959.33.

## 15. Explanation for Program Changes or Adjustments

This is a new data collection.

## 16. Plans for Tabulation, Publication, and Project Time Schedule

The formal contracts for the HCPS do not include providing any public reports, publications, or other public information releases.

The operational schedule for the HCPS pretest is shown in Table 5.

**Table 5. Operational schedule for HCPS field test**

| Pretest Activity | Start date | End date |
|---|---|---|
| Develop cognitive protocol | 1/21/13 | 1/25/13 |
| Select and contact health center sites | 7/8/13 | 7/26/13 |
| Conduct Round 1 of Pretest Interviews | 7/29/13 | 8/15/13 |
| Revise Questionnaire | 8/16/13 | 8/29/13 |
| Conduct Round 2 of Pretest Interviews | 8/30/13 | 9/12/13 |
| Revise Questionnaire | 9/13/13 | 9/19/13 |
| Conduct Round 3 Pretest Interviews | 9/20/13 | 10/10/13 |
| Revise and Finalize Questionnaire | 10/11/13 | 10/28/13 |

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

The expiration date for OMB approval of the information collection will be displayed on data collection instruments and materials. No special exception to this request is requested.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.