

**Supporting Statement for
A Qualitative Formative Research Study to Develop
a Transparent and Plain Language
“Facts for Consumers about Health IT Service Providers”**

A. Justification

1. Circumstances Making the Collection of Information Necessary

ONC is requesting an approval by OMB on a reinstatement with change to a previous approval, 0955-0002, which expired, October 31, 2012. One of the key goals of the Federal Health Information Technology Strategic Plan (Strategic Plan) is to inspire consumer trust and confidence in health information technology (health IT) and electronic health information exchange (eHIE) by protecting the confidentiality and integrity of health information through appropriate and enforceable federal policies. Informed patient choice is one way to ensure a trust relationship with patients for the success of electronic health information exchange. Recent recommendations by the Health Information Technology Policy Committee (HITPC) stress the importance of meaningful choice: that the patient understands how information will be shared and with whom and the potential consequences of deciding whether to share information or not. The recommendations also note that it is the person who has the treating relationship with the patient who is responsible for educating patients regarding how information will be shared and with whom, as well as obtaining and tracking patient choice. The recommendations further state that The Office of the National Coordinator for Health Information Technology (ONC) should provide resources and educational materials to providers to demonstrate and implement meaningful choice for patients.

The HIPAA Privacy Rule requires covered entities to make available a notice of privacy practices for protected health information (notice of privacy practices) to their patients or health plan members. The notice must, among other things, outline the purposes for which the covered entity is permitted to use and disclose health information, the rights of individuals with respect to their health information, the entities’ duties to protect that information, and the process for filing a complaint concerning possible violations of the Privacy Rule, such as an improper use or disclosure of information. The Privacy Rule requires that the notice be written in plain language, but studies have shown that these notices are often difficult for patients to understand due to their length and complexity.

The Federal Health IT Strategic Plan identifies the Fair Information Practice Principles (FIPPS) an important guidepost in the development of privacy policies and programs. Openness and Transparency is a key principle of fair information practices. As applied to health information technology by the Nationwide Privacy and Security Framework for

Electronic Exchange of Individually Identifiable Health Information, Openness and Transparency means that “[i]ndividuals should be able to understand what individually identifiable health information exists about them, how that individually identifiable health information is collected, used, and disclosed and whether and how they can exercise choice over such collections, uses, and disclosures.” The notice of privacy practices is a key component of fulfilling this principle. If patients cannot adequately understand the notice because of its length or complexity, then the use and disclosure of their health information is not open and transparent.

The Health Information Technology for Economic and Clinical Health Act (HITECH) requires modifications to the HIPAA rules that create additional patient rights. These modifications include the patient’s right to opt out of receiving fundraising communications and the patient’s right to restrict the sharing of the patient’s information with health plans for certain services for which the patient (or someone on the patient’s behalf) has paid the covered health care provider in full. In a Notice of Proposed Rulemaking published in the Federal Register on July 14, 2010, the Office for Civil Rights (OCR) proposed to require that these new patient rights be included in the notice of privacy practices. While the final rule is still in development, the proposed use of the notice of privacy practices to inform individuals of these rights heightens the need for covered entities to write notices in such a way that individuals can comprehend these rights and the availability of choice.

In written guidance, OCR informed covered health care providers that they may include a notice of their participation in eHIE within their notices of privacy practices. While the guidance does not require this integration, OCR notes that information about the types of disclosures made through eHIE and how the network is protected would be reflective of the openness and transparency principle. As providers continue to achieve Meaningful Use and exchange health information electronically, the notice of privacy practices will increasingly be used to inform patients of these uses and disclosures and the security of networked exchange.

2. Purpose and Use of Information Collection

This is a single study data collection. ONC will conduct qualitative formative research to develop content and a structure for a clear and useable model notice of privacy practices document. The content and structure for the information will enable covered entities to clearly articulate and patients to clearly understand the privacy and security policies and practices of vendors. With transparency and understanding, patients will make informed decisions on data sharing when the covered entity presents them with choices related to information sharing, such as sharing information through a health information exchange or not sending information to health insurance companies for payment purposes when they pay out of pocket.

ONC will seek input from a total of no more than 52 consumers. Testing will be conducted in six locations that cover the four geographic census regions and will include 1-2 Focus Groups with 10 participants each (up to 20 total), 1 90-minute, one-on-one, cognitive usability pre-test interview with 4 participants, and 4 90-minute, one-on-one, cognitive usability interviews seven participants at each of four sites, to

- assess and analyze consumer understanding, and
- develop the template content and design for an improved notice of privacy practices (NPP).

The data collection will provide ONC with information for developing content and a structure for an improved NPP with a focus on

- comprehension of the information,
- navigation through the information,
- comparison of covered entities' policies and practices, and
- an ability to make an informed decision and choice of covered entities' services.

With each round of qualitative formative research and based on consumer understanding and input, we will make iterative changes to develop the content, structure, and tone of the NPP. Ultimately, the NPP will enable consumers to understand and compare how covered entities use and protect their personal and health information and the covered entities policies and practices around use and protection so consumers can make informed decisions about sharing their individually identifiable health information for certain purposes.

3. Use of Improved Information Technology and Burden Reduction

ONC may consider improving information collection by using the technology of usability software. We will consider using a computer model and will consider incorporating usability software. Logs from usability software would track participants' onscreen navigation and use of the model without burdening participants with other time-tracking methods. The logs would collect information on the testing draft of the model in each round.

4. Efforts to Identify Duplication and Use of Similar Information

Conducting qualitative formative research to develop content for an improved NPP has never been done.

5. Impact on Small Businesses or Other Small Entities

There is no impact to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

52 respondents will participate in one-time 90 minute qualitative sessions as described in Section B.

There are no legal obstacles to reduce the burden

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

The request fully complies with the regulation.

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

A 60-day Federal Register Notice was published in the *Federal Register* on August, 28, 2012, vol. 77, No. 167; pp. 52033-52034. This qualitative formative research is being conducted to develop clear privacy and security content for a transparent NPP. The development is not currently part of a regulation being published.

9. Explanation of any Payment/Gift to Respondents

Each respondent will receive between \$75 and \$125 for participation in the qualitative formative study. We ask the market research testing facilities for the minimum rate needed to recruit subjects, and the rate varies by location. Recruiting individuals at a lower cost ultimately costs more due to increased time and level of difficulty in recruitment costs for the study.

10. Assurance of Confidentiality Provided to Respondents

Respondents will be informed that participation is completely voluntary. Each participant will read and sign a document explaining how privacy is maintained (Attachment C). To ensure the privacy of each of the 52 participants, we follow the following procedures.

- Respondents will only be identified by first name during the interview.
- No names will be used in any reports, and the reports will be made available to ONC staff, policymakers or other members of the public.
- Contact information (full name, address, telephone number) is maintained by the testing facility and will never be accessed or sought by ONC.
- Official access to the data will be controlled and no public access is allowed. The information will be kept in locked offices.
- The questionnaires and data collected during the interviews will be destroyed at the end of the project when there is no further data and analysis use for the information.

11. Justification for Sensitive Questions

We will not be asking participants any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, social security number and other matters like these that are commonly considered private.

To ensure diversity of our 52 respondents for each round in six geographically dispersed locations and to gauge understanding and usability of the NPP content, it is relevant and important to recruit with a balanced census distribution that represent a cross-section of consumers. To recruit for this study, we do ask potential respondents for their ethnicity and race. We will also recruit for a balanced distribution of the 52 participants across gender, education, age, and income. While we use questions such as these to recruit for this small sample of 52, we do not ask respondents sensitive questions like these as a part of the interview.

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

Each testing facility will keep track of the recruitment screening and scheduling burden hours. We anticipate that approximately 50% of consumers contacted for this study will qualify and agree to participate.

The estimated time to complete each participant screening is 15 minutes.

Each test session is 90 minutes (maximum).

Estimated Annualized Burden Table

Type of Respon-dent	Number of Respon-dents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours	Department of Labor Hourly Minimum Wage Rate	Total Respon-dent Cost
Screening						
Focus Group	40	1	15 minutes	10 hours	\$6.55/hour	\$65.50
Cognitive Testing	64	1	15 minutes	16 hours	\$6.55/hour	\$104.89
Selected						
Focus Group	20	1	90 minutes	30 hours	\$6.55/hour	\$196.50
Cognitive Testing	32	1	90 minutes	48 hours	\$6.55/hour	\$314.40
Total	104			104 hours		\$681.29

13. Estimates of other Total Annual Cost Burden to Respondents or record-keepers/Capital Costs

Estimates of other total annual cost burden to respondents or record-keepers/capital costs are not relevant to a single qualitative formative study of this size.

14. Annualized Cost to Federal Government

The approximate annualized cost of conducting this qualitative formative study to the federal government is \$340,009.50. This estimated figure includes site, recruitment, travel, labor, and other direct costs for a contractor who will conduct the cognitive usability tests.

15. Explanation for Program Changes or Adjustments

The previous collections under this program were used to develop and analyze a model privacy notice for Personal Health Records (PHRs). The model privacy notice for PHRs that resulted was voluntarily adopted by several PHR vendors. Due to the success of this information collection, we are proposing to revise the program to use the same focus group and cognitive usability interview testing process for the development of an improved notice of privacy practices.

16. Plans for Tabulation and Publication and Project Time Schedule

Due to the nature of this being a qualitative rather than quantitative study, tabulation, statistical manipulations, and complex analytical techniques are not relevant. We will not publish any data on the internet.

The data collected from the 52 participants in either focus groups or individual usability tests will be analyzed qualitatively with primary sources of notes taken during the interviews, debriefing notes, and usability software log reports. Analysts will identify critical incidents from the session that report

- perceptions of the participants about the NPP's layout, organization, and design,
- whether participants could find key pieces of information in the model document,
- whether participants could understand the information in the model document, and
- whether participants could form inferences about the information in the model document to make informed decisions about NPPs.

The qualitative analysis will be tied to questions that are answered either implicitly by the participants during the sessions or explicitly when directly asked by the test moderator.

We will conduct the 52 cognitive usability tests iteratively in six locations from November 2012 – August 2013, starting as soon as possible following OMB approval. With each test, we will analyze the qualitative data and make changes to the NPP content and structure. We plan to have an improved NPP developed by December 2013.

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

There is no reason the display of an OMB Expiration Date is inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.