

**Supporting Statement for
A Qualitative Formative Research Study to Develop
a Transparent and Plain Language
“Model Privacy PHRFact Sheet”**

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Obama administration’s domestic healthcare overhaul agenda and stimulus plan directly impacts and supports the mandate for The Office of the National Coordinator for Health Information Technology (ONC), a division of the Department of Health and Human Services (HHS). That mandate is to provide leadership for the strategic development and nationwide implementation for interoperable health information technology (health IT) by 2014. To effectively lead this effort, ONC must guide the strategic direction of technological implementation. ONC must also attend to the serious concerns of transparency, accountability, and increased openness in how the healthcare community and industry involved in healthcare handle, share, use, disseminate, and protect consumer health and personal information. In doing so, ONC must spearhead efforts on how the government and industry “package” privacy and security information so that consumers clearly understand policies and practices, uses of their information, and are able to make informed decisions.

In moving from a paper-based medical record environment to an electronic health record environment, it is expected that hospital expenses will go down, the risk of medical errors will lower, and the quality of care in our country will rise. However, moving health records to an electronic environment greatly increases the opportunity for security breaches, information leaks, and data losses. As the stimulus package nears completion, the national dialog on healthcare overhaul has significant foci on the critical and imminent need to attend to consumer privacy and security.

Of immediate interest is the Personal Health Record (PHR), a new health information technology and tool. PHR vendors such as Google Health, Microsoft Healthvault, WebMD, and Kaiser Permanente already provide PHRs as a service to consumers. PHRs enable consumers to manage, track, and share their health information and records in an electronic medium and web environment. They also contain very sensitive health and personal information. Consumer understanding of vendors’ privacy and security practices is critically important. The development of a transparent and clear model for PHR vendors to articulate to their customers their privacy and security policies is vital as more consumers move their health information online.

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 PHR privacy facts model document. The content and structure for the information will enable PHR vendors to clearly articulate and consumers to clearly understand the privacy and security policies and practices of vendors. With transparency and understanding, consumers will make informed decisions on whether to use a PHR and which vendors' practices work for their specific needs.

ONC will seek input from a total of 42 consumers through six iterative rounds of formative usability testing to

- assess and analyze consumer understanding, and
- develop the template content and design for a model PHR Fact Sheet.

The data collection will provide ONC with information for developing content and a structure for the model PHR Fact Sheet with a focus on

- comprehension of the information,
- navigation through the information,
- comparison of PHR vendor policies and practices, and
- an ability to make an informed decision and choice of PHR vendor and 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 PHR Fact Sheet. Ultimately, the PHR Fact Sheet will enable consumers to understand and compare how PHR vendors use and protect their personal and health information and PHR vendors' policies and practices around use and protection so consumers can make informed decisions about selecting and using PHRs.

Toward this end, ONC has contracted with the Kleimann Communication Group (KCG) to conduct this qualitative formative research project.

3. Use of Improved Information Technology and Burden Reduction

ONC will improve information collection by using the technology of usability software. Four of the six iterative rounds (66%) of usability testing will be conducted using a computer model and will incorporate usability software. (The other two of six rounds will be paper-based and not incorporate usability software.) Logs from usability software will track participants' onscreen navigation and use of the model without burdening

participants with other time-tracking methods. The logs will 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 a model PHR privacy fact sheet 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

42 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

This qualitative formative research is being conducted to develop clear privacy and security content for a transparent PHR Model Fact Sheet. The development is not currently part of a regulation being published.

9. Explanation of any Payment/Gift to Respondents

Each respondent will receive ~~between \$6075 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 42 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 42 respondents for each round in six geographically dispersed locations and to gauge understanding and usability of the PHR Model Fact Sheet content, it is relevant and important to recruit with a balanced census distribution that represent a cross-section of consumers who currently or eventually will use PHRs. 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 42 participants across gender, education, age, income, and familiarity with electronic health and PHRs. While we use questions such as these to recruit for this small sample of 42, 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

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
Total	Individuals	42	1	105/120	73 and 1/2

There are no costs to respondents for this study. All respondents are voluntary.

Annualized costs to respondents are not relevant for this single qualitative formative research study of 42 usability sessions.

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 cost of conducting this qualitative formative study to the federal government is \$140,560.00. This estimated figure includes site, recruitment, travel, labor, and other direct costs for Kleimann Communication Group who will conduct the cognitive usability tests.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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.

Each of the 42 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 PHR Model Fact Sheet'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 PHRs.

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 42 cognitive usability tests iteratively in six locations during 2009 as soon as possible following OMB approval. With each test, we will analyze the qualitative data and make changes to the PHR Model Fact Sheet content and structure. We plan to have a final PHR Model Fact Sheet developed by December 2009.

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.

B. Collection of Information

Please Note: Statistically significant sample size and statistical data analysis are not relevant to a qualitative formative study. Qualitative research uses small numbers. The relevant qualitative data collection procedures are described in this Section B.

1. Respondent Universe and Sampling Methods

This qualitative testing project will include a maximum of 42 respondents across six different testing locations relevant to census and the subject matter. The tentative testing locations include: Austin, TX; Minneapolis, MN; Providence, RI; San Diego, CA; Seattle, WA; and Tampa, FL. Participant recruiting will be conducted to ensure six to seven test subjects in each location who meet the eligibility requirements outlined in the recruitment package. To ensure diversity of respondents, each location will use a participant screener to recruit along U.S. census demographic statistics. In addition, the sample will include participants both familiar and unfamiliar with PHRs and participants who manage chronic health issues or disease for themselves or others. The participant recruitment package is included as Attachment B.

We anticipate that approximately 50% of consumers contacted for this study will qualify and be willing to participate. Assuming this percentage, we will need to screen 84 individuals to recruit 42 participants. This estimate is based on the professional research sites' recommendation per their recruiting process and the contractor's previous testing experience.

2. Procedures for the Collection of Information

ONC has contracted with Kleimann Communication Group (KCG), an experienced research and communications firm, to conduct the six rounds of iterative, one-on-one, cognitive usability testing. KCG will conduct 90-minute usability interviews with six to seven participants at each of six sites, for a total not to exceed 42 interviews. KCG will use professional testing and recruiting facilities for each round.

The professional testing and recruiting facilities include a testing room equipped with a one-way mirror, observation room, usability software, and audio/videotaping equipment. Trained and experienced KCG staff will serve as moderators, note-takers, and observers during the actual testing sessions.

Before each test, participants will read and sign a statement (Attachment C) confirming that participation is voluntary and stating how privacy is maintained. Each participant will fill out a brief demographic questionnaire to confirm and document the diversity of the 42 respondents (Attachment D).

KCG will conduct two paper-based rounds initially to develop content. KCG will then conduct four usability tests using an electronic format for more detailed comprehension, usability, and navigation data. During the 90-minute interview, participants will look at either a paper-based or online screen of the PHR Model Fact Sheet, provide their unguided impressions through a think-aloud protocol, and then answer focused questions regarding design, content, navigation, comprehension, and comparative decision-making.

The data collection is qualitative, and will be analyzed by using the following sources of information:

- Participant discussion of questions posed in the Moderator's Guide (Attachment A) during the sessions
- Notes taken during each session using a note taker's log of observations
- Debriefing notes taken by the note taker, moderator, and observer after each session
- Logs from usability software that tracks participants' onscreen navigation and use of the model for the online sessions
- DVDs/videotapes of the sessions (The sources listed above will be the primary sources of information. The videotaping will only be used to clarify responses as needed.)

As a qualitative study, analysts will identify critical incidents from the testing sessions that report

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

The 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 moderators.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Participants will be contacted by recruiting facilities via phone to schedule each of the 42 respondents at each of the six sites. To maximize response rate, test sites send a

confirmation letter to respondents in advance of the test date and then also call respondents the day prior to the test order to confirm participation and schedule.

4. Test of Procedures or Methods to be Undertaken

The proposed qualitative cognitive usability testing methodology of an unstructured think-aloud protocol followed by a series of focused, direct questions about the PHR Model Fact Sheet content and structure is a qualitative method used for many successful OMB-approved document development and information design cognitive usability testing projects with several government agencies. Quite different than conducting large quantitative, statistical studies or drug trials, this type of qualitative testing facilitates the development of clear, usable, and understandable information about serious and relevant health information based on consumer feedback and documented data. For examples of other KCG qualitative studies to develop clear information, please see:

- Internal Revenue Service
- OMB 1545-1349
- Department of Housing and Urban Development
- OMB 2528-0225

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statistical analysis is not relevant to a qualitative formative research project of this size.

Jodi Daniel, Director, Office of Policy and Research in the Office of the National Coordinator for Health Information Technology (ONC), is directing this qualitative formative research project through a contract with Kleimann Communication Group (KCG). The Project Officer is Kathleen Fyffe, Special Assistant, ONC. The KCG project team will design, conduct, and analyze the research and data. The KCG project team includes:

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