DATE: June 23, 2008

TO: Seleda Perryman, HHS

FROM: Sandra Hilfiker, ODPHP

RE: Request for OMB Clearance of Evaluation Study "Evaluation of a Prevention Information Prototype in the Context of a HRSA Community Health Center**"**, under ODPHP's Generic Clearance 0990-0281, Submission # 10

Statement of Need

The Office of Disease Prevention and Health Promotion (ODPHP) created a prototype of interactive digital health information to help Americans stay healthy. The prototype consists of several sets of interactive health information (text content, links and interactive tools) pertaining to specific disease prevention and health promotion topics. It has been designed to meet the needs of audiences with limited health literacy. This prototype has been integrated into www.healthfinder.gov as part of a redesign of the site. Because a majority of individuals with limited health literacy do not seek out health information online and are less likely to take preventive measures, it is important to incorporate prevention information and tools into contexts where they are already served. Community health centers provide an important gateway to reaching audiences with limited health literacy.

The purpose of the proposed data collection is to assess patient reactions to prevention messages from healthfinder.gov in the context of a community health center. Participants for the study will include 500 adult patients participating in a wellness program at Middlesex Community Health Center (part of the Baltimore Medical System) called *Putting Prevention into Practice*. The goal is to assess respondents' reactions, self efficacy, and behavioral outcomes as a result of receiving prevention messages on weight management and/or tobacco cessation. Data will be collected through a pre/post survey at the health center and a telephone survey with a subset of 200 participants implemented as a 30-day follow-up.

Intended Use of Information

The information collected will be used to:

- assist with assessing the success of an effort to have health center staff and providers promote the use of Internet based health information as the basis for patients' self-directed efforts to improve their health
- refine the original prevention messages provided in healthfinder.gov to better meet patient and health center staff needs

- demonstrate the capacity to merge informal prevention information communicated during routine visits with data from electronic medical records (EMR) in order to track behavioral changes that may impact routine health indicators

ICF International will conduct the study, summarize and interpret results, and produce a report to the Office of Disease Prevention and Health Promotion. Oversight for this research is provided by the Office of Disease Prevention and Health Promotion (coordinating office), the ICF's Institutional Review Board, and the Baltimore Medical System (BMS).

After patients complete pre-and post exam screening surveys a subset of patients (who have agreed to participate) will be contacted for a 30 day follow-up telephone survey.

Table 1. Telephone Survey Group Description

Type of Respondent	Form Name	No. of Respondents	No. of Responses	Average Burden Per Respondent	Total Burden Hours
Consumers	Pre-Survey	500	1	5 min/invited participant	42 hours
Consumers	Post-survey	500	1	5 minutes	42 hours
Consumers	30-Day Follow-up Telephone Survey	200	1	10 minutes	33 hours
Totals					117 hours

Information Collection Procedures

Health Center staff will enroll participants in the wellness program, *Putting Prevention into Practice*. Patients enrolled in *Putting Prevention into Practice* will choose to receive prevention messages during the Center visit on smoking cessation or weight management. The prevention messages will be derived from heatlhfinder.gov but will be provided through a number of channels including posters, interactions with health center staff, print materials, and the Web site itself. Health Center staff will be using the electronic medical record to document their conversations with patients on the prevention topics mentioned above.

Patients enrolled in the *Putting Prevention into Practice* program will be invited to participate in the 30-day follow-up survey in addition to completing a brief pre/post survey. The Pre/post surveys will be conducted over the course of an actual visit to the exam room and while patients wait. All survey instruments are designed to be minimally intrusive and easily administered. The front desk staff adds the patient identification numbers to pre-and post surveys at the time of the visit.

When ICF conducts the follow up calls, BMS will supply the study team with the roster of participants for the first 4 months with patient name, the prevention measure they signed up for (weight management or smoking cessation), and their phone number. The Center will maintain a separate list of participating patients' ID numbers matched with names. After conducting the telephone survey, ICF will give these data back to BMS so that they can remove patient name and replace it with patient ID. The data ICF gets back from BMS will be anonymous (to ICF)

and will be merged with initial pre/post survey data based on ID. The ICF composite survey database will only have patient ID and no names.

A confidentiality statement is included on written instruments that are completed during the pre- and post clinical exam of encounters. In the 30 day follow-up telephone survey, interviewers will read the statement about confidentiality and study sponsorship. To maximize the survey response rates, ICF is prepared to make up to five calls per identified patient during the two-month study time. Telephone interviews will be composed using language at an appropriate grade or reading level. The pre-post exam survey instruments and 30 day follow-up survey has been reviewed and approved by the ICF Institutional Review Board (IRB).

Anonymity Safeguards. As noted above, information that could be used to identify individual participants will not be provided to ICF, HHS, or any of its agencies. Such listings will remain in the sole possession of BMS/Middlesex Health Center staff and only be used to match survey responses with medical record data. Compiled and merged data □stripped of identifiers□ will be returned to ICF's study team for analytical purposes. No names will be associated with individuals' comments or responses in any survey reports. All information obtained during telephone surveys will be physically recorded on those forms. Physical forms will be maintained under lock and key by ICF and disposed of subsequent to the study according to the agency's standard record keeping protocol.

We do not plan to provide a monetary incentive to patients who participate in the study. The instruments are very brief so there should be minimal burden to the participants' time.

Justification for Proposed Collection Methodology

As previously mentioned, ODPHP seeks clearance for conducting brief pre/post surveys and follow-up telephone surveys with patients of the Middlesex Community Health Center. The patients for this study will be involved in the health and wellness program, *Putting Prevention into Practice*. The proposed study attempts to answer the following research questions:

- RQ1: What are the information needs of patients on the topics of weight management and smoking cessation?
- RQ2: Do patients find the prevention information in heatlhfinder.gov useful and appropriate?
- RQ3: Does the prevention information provided in healthfinder.gov increase patients' self-efficacy regarding taking steps to manage their weight or quit smoking within the time frame of a health center visit?
- RQ4: Does the prevention information provided in healthfinder.gov increase patients' self-efficacy overtime (30 day period) regarding taking steps to manage their weight or quit smoking?
- RQ5: As a result of receiving prevention information from healthfinder.gov, do patients take steps to mange their weight or quit smoking within a 30 day time period?

Estimated Response Burden

The pre/post surveys are estimated to take 5 minutes each per respondent for a total of 10 minutes. We estimate 500 total participants, so the total estimated response burden is (500 patients X 10 minutes = 5,000 minutes) approximately 84 hours.

The 30-day follow-up telephone survey is estimated to take 10 minutes per respondent. We estimate a total of 200 participants, so the total estimated response burden is (200 patients X 10 minutes = 2,000 minutes) 33 hours.

ESTIMATED TOTAL BURDEN HOURS for surveys = 117 hours

The cumulative number of hours used under OMB No. 0990-0281 is 1,531.

APPENDICES [IN SEPARATE FILES]

1. Participant pre survey
2. Participant post survey
3. Telephone interview and script